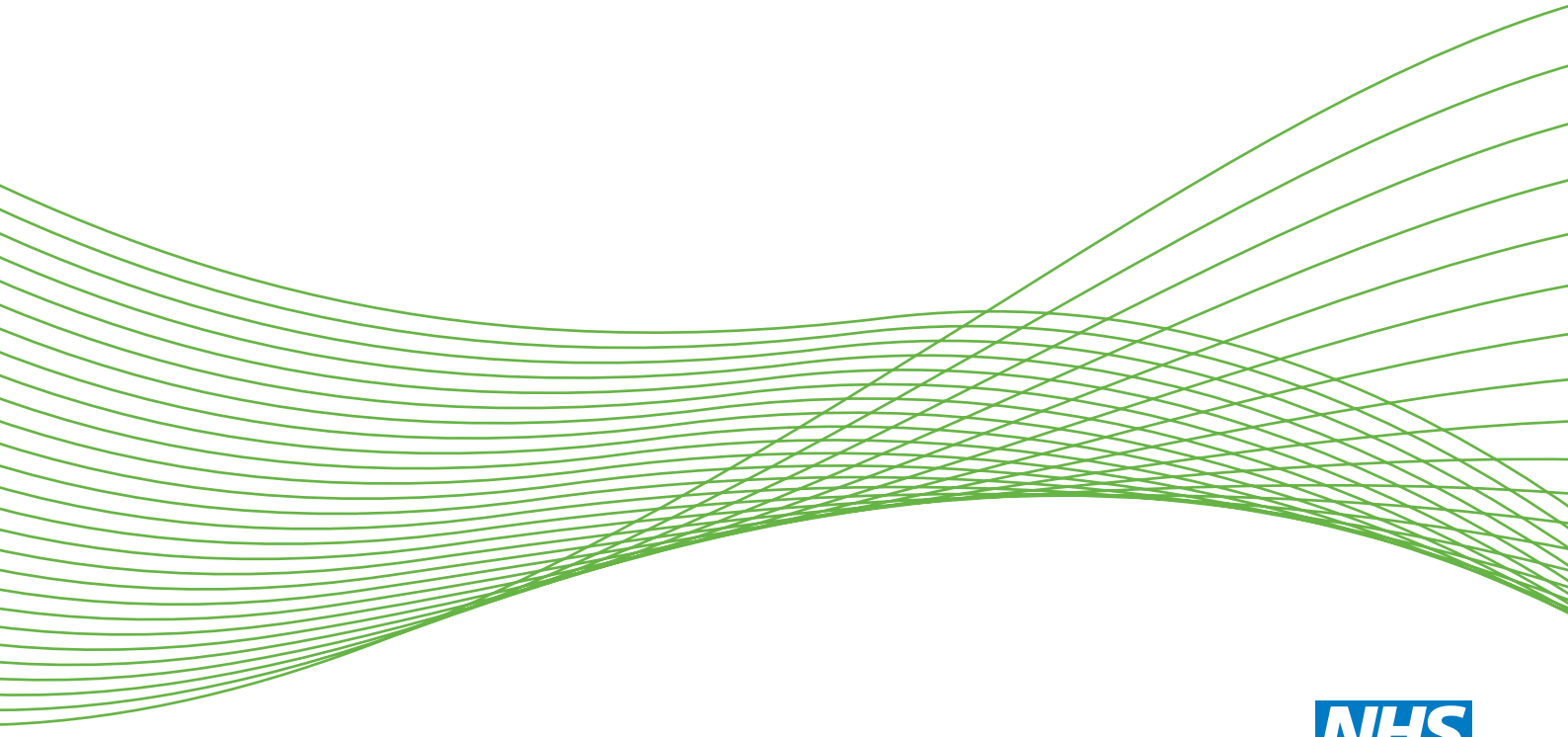
HEALTH SERVICES AND DELIVERY RESEARCH

VOLUME 2 ISSUE 23 JULY 2014
ISSN 2050-4349

# Facilitating technology adoption in the NHS: negotiating the organisational and policy context – a qualitative study

*Sue Llewellyn, Rob Procter, Gill Harvey, Gregory Maniatopoulos and Alan Boyd*



National Institute for Health Research

DOI 10.3310/hsdr02230

# Facilitating technology adoption in the NHS: negotiating the organisational and policy context – a qualitative study

Sue Llewellyn,[1]* Rob Procter,[2] Gill Harvey,[1] Gregory Maniatopoulos[1] and Alan Boyd[1]

[1]Manchester Business School, University of Manchester, Manchester, UK
[2]Manchester eResearch Centre, University of Manchester, Manchester, UK

*Corresponding author

**Declared competing interests of authors:** none

Published July 2014
DOI: 10.3310/hsdr02230

This report should be referenced as follows:

Llewellyn S, Procter R, Harvey G, Maniatopoulos G, Boyd A. Facilitating technology adoption in the NHS: negotiating the organisational and policy context – a qualitative study. *Health Serv Deliv Res* 2014;**2**(23).

# Health Services and Delivery Research

ISSN 2050-4349 (Print)

ISSN 2050-4357 (Online)

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

The full HS&DR archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hsdr. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

### Criteria for inclusion in the *Health Services and Delivery Research* journal

Reports are published in *Health Services and Delivery Research* (HS&DR) if (1) they have resulted from work for the HS&DR programme or programmes which preceded the HS&DR programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

### HS&DR programme

The Health Services and Delivery Research (HS&DR) programme, part of the National Institute for Health Research (NIHR), was established to fund a broad range of research. It combines the strengths and contributions of two previous NIHR research programmes: the Health Services Research (HSR) programme and the Service Delivery and Organisation (SDO) programme, which were merged in January 2012.

The HS&DR programme aims to produce rigorous and relevant evidence on the quality, access and organisation of health services including costs and outcomes, as well as research on implementation. The programme will enhance the strategic focus on research that matters to the NHS and is keen to support ambitious evaluative research to improve health services.

For more information about the HS&DR programme please visit the website: www.netscc.ac.uk/hsdr/

### This report

The research reported in this issue of the journal was funded by the HS&DR programme or one of its proceeding programmes as project number 08/1820/254. The contractual start date was in October 2009. The final report began editorial review in March 2013 and was accepted for publication in September 2013. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HS&DR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.



Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).

# Abstract

## Facilitating technology adoption in the NHS: negotiating the organisational and policy context – a qualitative study

Sue Llewellyn,[1]* Rob Procter,[2] Gill Harvey,[1]
Gregory Maniatopoulos[1] and Alan Boyd[1]

[1]Manchester Business School, University of Manchester, Manchester, UK
[2]Manchester eResearch Centre, University of Manchester, Manchester, UK

*Corresponding author

**Background:** Proven clinical effectiveness and patient safety are insufficient to ensure adoption and implementation of new clinical technologies. Despite current government policy, clinical technologies are not yet demand-led through commissioning. Hence, adoption and implementation relies on providers. Introducing new technologies initially raises providers' costs as they necessitate training, alter patient pathways and change patient management, and may lead to reduced patient throughput in the short term. The current funding regime for providers – Payment by Results (PbR) – rewards activity. It is not surprising, therefore, that providers often see new technologies as risky.

**Objectives:** This study investigated the organisational and policy context for the adoption and implementation of clinical technologies, because this context may present barriers that slow – or even prevent – uptake. The research focused on three clinical technologies: insulin pump therapy (IPT); breast lymph node assay (BLNA), a diagnostic tool for metastases; and ultrawide field retinal imaging (UFRI). The implementation of these technologies had been supported by NHS Technology Adoption Centre (NTAC).

**Methods:** The research method was qualitative case studies of these three clinical technologies. The primary data collection technique was semistructured interviews of NTAC staff, clinicians, managers and commissioners, supplemented by documentary evidence, participant and non-participant observation of meetings and videos. For IPT, we also conducted a survey of clinicians and analysed anonymised e-mails from patients.

**Results:** NHS providers did not perceive any central 'push' from the Department of Health or the National Institute for Health and Care Excellence (NICE) to adopt, implement or diffuse new clinical technologies. There is a 'bottom-up' adoption culture: any trust could choose to adopt any, all or none of the three clinical technologies we investigated. This is undesirable, as clinically efficacious technologies should be equally available to all patients. Where there is NICE guidance, this acted as an enabler for adoption, but some trusts still did not offer IPT despite this. We found that PbR could be a major obstacle to adoption. Our evidence also indicates that, contrary to its intention, commissioning practice is more of a barrier than an enabler of innovation. Protracted negotiations over funding between providers and commissioners delayed implementation of BLNA and IPT. Organisational power and politics between hospitals and community-based services was a significant barrier for adoption of UFRI. Clinicians outside of specialist ophthalmology centres did not understand the clinical utility of UFRI (e.g. its diagnostic potential or how and when to use it).

**Conclusions:** NTAC was successful in assisting trusts over the generic organisational barriers outlined above, particularly with regard to taking responsibility for the logistics of implementation, negotiating new patient pathways and ways of working with relevant stakeholders, and using their skills in project management and stakeholder engagement to drive processes forward. Where there were major obstacles, however, the NTAC process stalled. 'Bottom-up' adoption at individual trusts needs to be linked into wider national processes that offer vision, some central direction, further assessment and evaluation, and the infrastructure to ensure diffusion to sites that have the capabilities and capacities to best utilise the clinical technology.

**Funding:** The National Institute for Health Research Health Services and Delivery Research programme.

# Contents

# List of tables

# List of abbreviations

| | |
|---|---|
| AHSC | Academic Health Science Centre |
| AHSN | Academic Health Sciences Network |
| ANT | actor-network theory |
| BLNA | breast lymph node assay |
| CCG | Clinical Commissioning Group |
| CEP | Centre for Evidence-based Purchasing |
| CIED | cardiac implantable electrical device |
| CLAHRC | Collaborations for Leadership in Applied Health Research and Care |
| COT | Community Ophthalmology Team |
| CQUIN | Commissioning for Quality and Innovation |
| CSII | continuous subcutaneous insulin infusion |
| DRG | diagnostic-related group |
| EU | European Union |
| FDA | Food and Drug Administration |
| GP | general practitioner |
| $HbA_{1c}$ | glycated haemoglobin |
| HIEC | Health Innovation and Education Cluster |
| HRG | Healthcare Resource Group |
| HSO | 'high street' optometrist |
| HTA | health technology assessment |
| HTWT | How to Why to |
| ICT | information and communication technologies |
| IPC | infection prevention and control |
| IPT | insulin pump therapy |
| IS1 | implementation site 1 |
| IS2 | implementation site 2 |
| IS3 | implementation site 3 |
| IT | information technology |
| MDI | multiple daily injection |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| MS | mentor site |
| NHS IQ | NHS Improving Quality |
| NHSC | National Horizon Scanning Centre |
| NHSI | NHS Institute for Innovation and Improvement |
| NIC | National Institute for Health and Care Excellence Implementation Collaborative |
| NICE | National Institute for Health and Care Excellence |
| NIHR | National Institute for Health Research |
| NIS | non-implementation site |
| NTAC | NHS Technology Adoption Centre |
| OSNA | one-step nucleic acid amplification |
| PbR | Payment by Results |
| PCT | primary care trust |
| QIPP | Quality, Innovation, Productivity and Prevention |
| SHA | Strategic Health Authority |
| SME | small- or medium-sized enterprise |
| TC | tertiary centre |
| UFRI | ultrawide field retinal imaging |
| WIS | withdrawn implementation site |

# Plain English summary

The British NHS is a slow and late adopter of clinical technologies. If this is not remedied it will increasingly become a performance issue for health care. Sir Bruce Keogh, the current NHS Medical Director, commented in 2012: 'Even with hard evidence of superior efficacy it generally takes around 15 years … for widespread adoption of a new intervention'.

This research aims to discover the organisational and policy barriers (and enablers) for technology adoption and implementation. Technology adoption is the decision to deploy the technology in a care setting. Implementation is bringing the technology into routine use and ensuring that it continues to be used.

We undertook case studies to investigate three clinical technologies: ultrawide field retinal imaging (UFRI); insulin pump therapy (IPT); and a breast lymph node assay (BLNA). We found that 'Payment by Results' (PbR; the present NHS funding system) was a major obstacle to the adoption and implementation of UFRI and BLNA. Our evidence also indicates that, contrary to its intention, current commissioning practice is more of a barrier than an enabler for technology adoption. Protracted negotiations over funding between providers and commissioners delayed the implementation of BLNA and IPT. Organisational power and politics between hospitals and community-based services were significant barriers to the adoption of UFRI.

Overall, we concluded that a greater degree of national policy direction is required to overcome these barriers and bring more coherence to technology adoption and implementation.

# Scientific summary

## Background

New clinical technologies have the potential to bring important benefits to health care, but adoption and implementation have not been straightforward. Diffusion of technical innovations across the NHS has been acknowledged to be uncoordinated and sometimes slow. Financial considerations are a key influence on investment decisions, and there can be uncertainty as new technologies may not be covered by national Payment by Results (PbR) tariffs. Putting this alongside the typically limited evidence base and the prospect of what may be a complex implementation task, it may be that NHS managers perceive adopting new technology as risky. Adapting implementation to the wider organisational and social context is also likely to be important.

This study addresses a research gap on how organisational factors shape the take-up of new technology in the NHS by investigating technology adoption projects supported by NHS Technology Adoption Centre (NTAC). NTAC projects focus on technologies that have the potential to substantially improve services but have not achieved optimal levels of uptake. NTAC chooses three to four implementation sites to cover different adoption and implementation problems. One NTAC staff member is assigned to each site and becomes the project implementation manager. Implementation projects follow project management and stakeholder engagement principles. NTAC emphasises that an implementation project is a means to full implementation, not a process that precedes a decision on whether or not to implement. Learning across all implementation sites is distilled into an online How to Why to (HTWT) clinical technology guide intended as an informational resource for subsequent adopters. Each guide contains a technology-specific business case template for securing approval for adoption from senior managers in both the trust that provides the service and the primary care trusts (PCTs) that commission it. Since this research ended, there have been major NHS reforms which, inter alia, replaced PCTs with Clinical Commissioning Groups.

## Objectives

The following research questions are addressed:

1. What are the main organisational and decision-making processes and challenges specific to the adoption of the trial project technologies? What are the barriers and enabling factors?

    i. Are processes for adoption generic or do the different types of technology require their own processes?
    ii. What role does the wider commissioning process play?

2. Actor roles:

    i. What is the role of the technology producer in supporting adoption in health-care organisations?
    ii. Facilitator organisation/NTAC:

        – How does the presence of and intervention by NTAC impact on the process of adoption within the institution?
        – Does the involvement of NTAC have an impact on the sustainability of adoption? Does the technology remain embedded after NTAC withdraws? Can the issues and processes that cause it to continue or fail to remain embedded be identified?
        – What information can be gathered from the NTAC project to assess the wider impact on how implementation is managed?

iii. Is it possible to identify best practice(s) for ensuring technology adoption? Are there key roles for managers and other decision-makers (e.g. clinicians, board members, patients)?

## Methods

The primary research method was qualitative case studies supplemented by a survey. The case studies focused on three clinical technologies that NTAC identified as presenting the most complex and puzzling problems for adoption and subsequent implementation: insulin pump therapy (IPT), also sometimes called continuous subcutaneous insulin infusion (CSII); breast lymph node assay (BLNA), a diagnostic tool for metastases; and another diagnostic tool, ultrawide field retinal imaging (UFRI).

We conducted 77 semistructured interviews with key clinicians and managers in the implementation project networks. All interviews were recorded and transcribed. We also collected background documentary evidence including sources relating to NTAC's decisions to accept particular trusts as implementation sites; notes of participant and non-participant observations of meetings at trusts and of NTAC-organised awaydays for project stakeholders; and internal trust or commissioner documents on technical or funding issues. Our online survey of a network of UK clinicians actively engaged in trying to increase IPT uptake had a 28% (91/320) response rate. Anonymised e-mails from people who had contacted a patient information and support group for IPT were also analysed. In addition, we interviewed four NTAC staff and filmed seven NHS trust staff using online HTWT guides produced by NTAC.

The analysis of the qualitative case study data was iterative using thematic analysis. Core themes were identified inductively within each setting then verified or qualified through comparisons between individual participants, sites and technologies. Frequency tables and cross-tabulations of categorical and ordinal survey data were produced. Free-text comments were triangulated with the themes emerging from the case studies. The videos were analysed by observing the path through the website taken by the user and summarising what users said. Key themes from across all of the user sessions were then identified.

## Findings

### *Generic policy barriers/issues*

Neither provider nor commissioner staff perceives any central 'push' from the Department of Health or the National Institute for Health and Care Excellence (NICE) to adopt, implement or diffuse new clinical technologies.

There is a 'bottom-up' adoption culture – any trust could choose to adopt any, all or none of the three clinical technologies we investigated. This is undesirable as clinically efficacious technologies should be equally available to all patients. For UFRI, this ad hoc approach to adoption was a significant issue as the technology was not 'domesticated'. Clinicians outside of recognised specialist ophthalmology centres did not understand the clinical utility of UFRI (e.g. its diagnostic potential or how and when to use it). This highlights the issue that any bottom-up adoption at individual trust level needs to be linked into wider national processes that offer vision, some central direction, further assessment and evaluation, and the infrastructure to ensure diffusion to sites that have the capabilities and capacities to best utilise the clinical technology.

Payment by Results is a significant generic policy barrier as, within the context of payment for activity, trusts require a business case based on short-term income generation. For example, BLNA brings clear patient benefits. Clinicians were very supportive and there are significant savings for the health economy, but under PbR there is loss of income for the trusts as only one operation is carried out rather than two. Moreover, there is no tariff for a new technology, no clear route to the Department of Health to provide evidence to create a new tariff and, often, no incentive to exert pressure for a tariff to be generated.

For example, for IPT, once the NICE guidance was issued, trusts were usually, but not always, able to persuade the PCT to fund the actual costs of the purchase of the pump and ongoing consumables if the patient concerned met the clinical criteria. However, trusts argued that there were 'infrastructure' costs that the PCT would not meet (e.g. funding for an IPT pump nurse specialist). As the tariff is based on national average costs (rather than trust-incurred actual costs), there is a risk for the trusts in pressing for a tariff as this may not cover their actual costs.

### *Generic organisational barriers/issues*

Within trusts, 'clinical technology adoption and implementation' is not in anyone's job description. Initiators for adoption were sometimes clinical, sometimes managerial. If the champion was a clinician, the process (submission of a business case) was rather alien; this, in itself, could be enough to deter active adoption and implementation. Any initiative was voluntary and often executed, at least in part, outside of normal working hours. Responsibility for ongoing projects was usually limited to a self-nominated small group (two or three doctors or nurses or both). These informal 'implementation groups' often encountered resistance from other members of staff. There was no clear evidence, even for 'active implementers', that changes were significant. For example, out of approximately 300 consultants who characterise themselves as active implementers of IPT, 91 responded to our survey on the extent of increased uptake. At the current time, of those 91 'active implementers', only 35% were at trusts with uptake levels near to or over the NICE guideline (i.e. 10–15% uptake of IPT or higher). Of 62 network members at trusts who 3 years ago had only 0–5% of patients on IPT, only 47% had managed to raise this level to above 5%.

Clinical technology adoption and implementation may change the patient pathway, require new ways of working and demand new skills. In the short term, while organisational processes are redesigned and staff become accustomed to different work practices, this leads to decreased patient throughput (and associated loss of income under PbR – see above). Also, these new work practices may cross intraorganisational boundaries making agreement difficult without goodwill on both sides. For example, to carry out the intraoperative BLNA, a histopathologist must be available to carry out the test immediately, limiting his or her capacity to carry out his or her normal workload. Theatre staff were reported to be sometimes resistant to the new procedure as it introduced uncertainty into theatre scheduling. If a patient is 'node positive', operations scheduled for later in the list would be delayed and so finish later than anticipated. The breast surgeons also had to undergo training; it was reported that if they were not supportive, the BLNA initiative would not progress. In consequence of the above, there is a significant cost for early adopters in the sense that they are forging a path for later adopters to follow and solving complex adoption problems without any pre-existing guidance, excepting any provided by the mentor site (MS). There is no start-up funding available for early adopters, so projects were sometimes pump-primed (or fully funded) by individual clinicians through their 'soft research money', charitable donations or even money solicited from patients who had benefited from the technology concerned.

Implementation, beyond initial adoption, could not proceed successfully without a degree of project management and the involvement of a wide group of stakeholders. Project management and the ability to generate stakeholder engagement are not skills that are always held by clinicians (or managers) in the NHS. Even implementation projects that generated considerable enthusiasm did not diffuse knowledge and 'take-up' beyond the immediate locale.

### *NHS Technology Adoption Centre successes*

For IPT and BLNA, the NTAC 'on the ground' process was, generally, very welcome. Respondents spoke of NTAC as 'being a catalyst', 'imposing a framework and timetable' and 'bringing everyone together, even the PCT'. Where an enthusiastic clinical lead had made some progress, NTAC channelled this enthusiasm into well-defined activities and set milestones and an end date for the project.

NHS Technology Adoption Centre was successful in assisting the trusts in addressing generic organisational barriers outlined above, particularly with regard to taking responsibility for logistics of implementation;

negotiating new patient pathways and ways of working with relevant stakeholders; and using their skills in project management and stakeholder engagement to drive implementation processes forward.

The NTAC's facilitation of adoption projects provides a space for social learning among the various stakeholder groups with, often, quite different ways of making sense of adoption issues. This is important in building consensus to identify new patient pathways, skills and work practices.

### *Limitations of the NHS Technology Adoption Centre process*

For UFRI, the process failed. Two implementation sites pulled out before start-up, having misunderstood the capability of the technology. The remaining site decided later that the technology was too expensive and did not 'fit' its pre-existing patient pathway. The project was disbanded.

There were some specific staffing problems on the UFRI project, which contributed to its early closure, but, disregarding these, it is very doubtful if the NTAC process could have resolved the very difficult implementation issues associated with this technology. The lack of agreement on the most appropriate location, the complex training issues involved in its use by optometrists, the lack of consensus on clinical utility and, if the technology was adopted, the PbR implications of possible loss of income in the trusts all conspired to place this technology outside of the realistic scope of NTAC. This is an example of a technology for which the efficacy can be properly assessed only in specialist centres or within the context of Academic Health Sciences Networks (AHSNs). This project found examples of successful implementation and business cases for UFRI only at specialist centres.

From the online survey, 46% of consultants interested in IPT adoption had not heard of NTAC. Only three consultants had used the HTWT guide to develop a business case to present to their trust and the majority (54%) were neutral with regard to the helpfulness of the guide. The qualitative evidence also indicates that the HTWT guides were not widely used and were unlikely to substitute for concrete NTAC support for implementation at the trusts. The interview data indicate that clinicians wish to discuss adoption with colleagues who have prior experience of success with the technology concerned. If possible, they want to 'go and see' the technology in use.

Of those who knew of the online HTWT guide, 96% of consultants had used it as an informational resource. However, the guide was valued only to a degree: 34% of consultants found the IPT guide 'somewhat helpful' or 'extremely helpful'.

The NTAC process does not address diffusion across the NHS as a whole. The HTWT guides were designed to encourage diffusion but there is little evidence of success in this.

### *Negotiating barriers*

Different sources 'pushed' for the adoption of each technology. Patients had a significant voice over IPT. There is some evidence that the rate of adoption of this technology responds to patient demand. Currently there is limited patient awareness of BLNA, and clinicians are the main instigators for adoption. Outside of specialist centres, knowledge of the potential of UFRI was limited, and industry is the primary source of an adoption 'push'.

For BLNA and IPT there is evidence that, where this impetus for adoption is augmented by other 'enablers' (e.g. the NICE guideline for IPT or agreement between the histopathologists and breast surgeons for BLNA), then some of the *organisational* barriers to implementation (see above) can be overcome.

National Technology Adoption Centre skills in project management and stakeholder engagement added further momentum to implementation processes. There is evidence that NTAC's 'on the ground' active commitment to projects worked to overcome organisational politics, prevented delays and stalling and set realistic timetables.

These enabling processes did not, however, overcome policy barriers. Specifically, there was no evidence of the trusts working with commissioners to negotiate new tariffs, although with BLNA a pass-through payment had been negotiated at one site. There was very little evidence that a 'bottom-up adoption culture' could enable the diffusion of clinical technologies beyond the trusts engaged in implementation projects.

## Conclusions

Although there were definite enabling factors that could be mobilised to overcome generic organisational barriers, without central policy direction for clinical technology adoption, wider diffusion of efficacious clinical technologies could not be guaranteed. Whenever there is a clear and coherent national strategy supported with appropriate infrastructure and resources, for clinical technology adoption, implementation and diffusion, NTAC-like project management and stakeholder engagement skills are likely to be successful.

## Funding

Funding for this study was provided by the Health Services and Delivery Research programme of the National Institute for Health Research.

# Chapter 1 Background and policy context

New clinical technologies have the potential to bring important benefits to health care, by improving effectiveness, efficiency and patient safety without increasing costs.[1] Although subject to much uncertainty, it has been estimated that a 3% growth in expenditure on new technology could produce a 3% growth in NHS productivity.[2] Furthermore, modern technologies may radically reshape health care, shifting the focus from expensive 'downstream' treatment of illness at a late stage towards lower cost 'upstream' health promotion and disease prevention interventions.[3] For example, 'active assistance' technologies can assist members of the public to understand and maintain their own well-being,[4] 'persuasive' technologies can facilitate health promotion,[5] and technologies for 'near-patient' (or 'point-of-care') testing[6] can shift activity from secondary care to primary care settings.

Achieving an optimal spread of new clinical technologies into health care has, however, proved to be far from straightforward. On the one hand, new technologies may be adopted rapidly and enthusiastically into routine practice, only for subsequent research to show no evidence of benefit over existing technologies, or even potential for harm (electronic fetal heart rate monitoring during labour for low-risk pregnancies being just one of a number of examples).[7] Furthermore, there are cost implications – developments in drugs and medical devices have been a major driver of growth in spending on health care,[8] and even if a technology enables cost savings over the medium to long term, additional capital is required in the short term, in order to purchase and install equipment and train staff to use it.

On the other hand, even in the USA, where expenditure on health-care technology is higher than in any other country, many technologies that have been proven to be effective have not been adopted fully.[9] Spending per capita in the UK has been much lower than in North America, Switzerland, Scandinavia and Germany,[10] with NHS investment in technology perhaps having been constrained by lack of funds.[11] Diffusion of technical innovations across the NHS has also been acknowledged to be uncoordinated, and the pace can also be slow, potentially denying benefits to patients.[1] Financial considerations are a key influence on investment decisions by NHS service providers, so the funding system is important. Reimbursement for most major procedures in acute hospitals takes the form of national tariffs determined by the Payment by Results (PbR) system.[12] There is some flexibility for local tariffs to be negotiated between individual trusts and commissioning organisations in order to take account of technological developments, but this introduces uncertainty. Putting this alongside the typically limited evidence base and the prospect of what may be a complex implementation task, it may be that adopting new technology is perceived as risky by NHS managers.

There is strong evidence from research in the private sector that the successful implementation of technology depends on negotiating the changes this requires to staff activities and adapting implementation to the wider organisational and social context. Yet there has been little research on how take-up of new technology in the NHS is shaped by organisational factors.[13] The study described in this report helps to fill this gap, by investigating the factors affecting projects supported by NHS Technology Adoption Centre (NTAC). NTAC projects aim to facilitate the adoption of non-pharmaceutical technologies in NHS organisations. They focus on technologies that have the potential to substantially improve health-care services, ideally supported by evidence from a formal appraisal, but have not achieved optimal levels of uptake. See *Chapter 4* for further information about NTAC.

The specific aims of the study are to:

1. understand the policy, organisational and cognitive barriers and resolve cross-boundary issues, including:

    i. identifying the root causes of risk perceptions over technology adoption among trusts involved in the NTAC projects
    ii. assessing the extent to which PbR is creating barriers to technology adoption and implementation

2. map out the network of actors required for successful technology adoption.

The objectives of the study are to:

1. produce recommendations on 'what needs to change' for successful technology adoption:

    i. addressing any misguided perceptions of risk through recommendations about communication and alleviating real risk (e.g. of income loss) through recommendations about cross-boundary negotiations
    ii. make recommendations of how local PbR flexibilities can be enhanced, if PbR is found to be too rigid

2. enhance actor roles

    i. identify any new boundary-spanning roles required to facilitate technology transfer along the adoption pathway
    ii. work closely with NTAC to ensure that this research dovetails with its agenda.

The study addresses the following research questions:

1. What are the main organisational and decision-making processes and challenges specific to the adoption of the trial project technologies? What are the barriers and enabling factors?

    i. Are processes for adoption generic or do the different types of technology require their own processes?
    ii. What role does the wider commissioning process play?

2. Actor roles:

    i. What is the role of the technology producer in supporting adoption in health-care organisations?
    ii. Facilitator organisation/NTAC:

        – How does the presence of and intervention by NTAC impact on the process of adoption within the institution?
        – Does the involvement of NTAC have an impact on the sustainability of adoption? Does the technology remain embedded after NTAC withdraws? Can the issues and processes that cause it to continue or fail to remain embedded be identified?
        – What information can be gathered from the NTAC project to assess the wider impact on how implementation is managed?

    iii. Is it possible to identify best practice(s) for ensuring technology adoption? Are there key roles for managers and other decision-makers (e.g. clinicians, board members, patients)?

The next two sections of this chapter clarify what constitutes clinical technology by giving an overview of different types of technology (see *Types of clinical technology*); and what the technology adoption process is by briefly discussing different conceptualisations of the process (see *The technology adoption process*). The final section provides information about the organisational and policy context for technology adoption in the NHS during the period of the study data collection (see *Organisational and policy landscape for technology innovation and adoption in the NHS*). This context has since changed somewhat with the advent of a new government and restructuring of the NHS. The consequences of key changes are discussed in *Chapter 8*.

*Chapter 2* reviews recent research in order to highlight issues that are most pertinent to NHS technology adoption. *Chapter 3* provides an underpinning for the research design used in the study by summarising theories relevant to technology adoption in the NHS. *Chapter 4* describes the NTAC approach to technology implementation and how it plays out in practice. Each of the following three chapters reports a case study of the implementation of a new technology. The final chapter discusses all of the findings and draws conclusions from them.

## Types of clinical technology

Clinical technologies can be thought of as encompassing all of the methods used in order to address health issues, including drugs, devices, procedures, and organisational and support systems.[14] Technologies can thus be 'low-tech' as well as 'high-tech', and are not limited to equipment. Clinical technologies include both medical and non-medical technologies, such as those for nursing care. The focus of our research is on clinical devices, procedures and associated support systems. NTAC itself defines technologies as treatments, devices and diagnostic tools.

There is such a wide variety of medical devices that even a summary definition which attempts to be comprehensive is lengthy:

*A medical device is any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software or material whose primary intended action is not achieved solely by pharmacological, immunological or metabolic means, and that is intended for human beings for:*

- *the diagnosis, prevention, monitoring, treatment or alleviation of disease*
- *the diagnosis, prevention, monitoring, treatment, alleviation of, or compensation for an injury*
- *the investigation, replacement, modification, or support of the anatomy or of a physiological process*
- *supporting or sustaining life*
- *controlling conception*
- *disinfecting medical devices*
- *providing information for medical or diagnostic purposes by means of an in vitro examination of specimens derived from the human body.*[15]

Medical devices include medical aids, such as wound-care products; artificial body parts, such as hip prostheses; and technical equipment, such as magnetic resonance imaging (MRI) scanners.[16] Simple devices such as thermometers, scales, latex gloves, wound dressings and beds are commonly used, and so clinical procedures can involve many devices.[17]

Interventional procedures for diagnosis or treatment involve an incision, puncture, entry into a body cavity or the use of electromagnetic radiation.[18] 'New' procedures span a spectrum of innovation from minor adaptations of existing practice, or applying an existing procedure in a new area, through to major innovations that are genuinely novel.[19]

Adoption decisions regarding interventional procedures and medical devices are more complex than for pharmaceuticals for a variety of reasons:[19] outcomes often depend on operator skill, with a learning curve to be negotiated; health technology assessment (HTA) processes have only recently been established; additional physical infrastructure is often required; and good quality data on cost-effectiveness is often not available. In addition, medical devices have a relatively short product life cycle (2–10 years) and prices are prone to vary over time, whereas interventional procedures are generally delivered to a heterogeneous patient population.

Innovative health-care technologies can include new models of care and ways of organising services and staff, such as nurse-led care, integrated transmural care across the primary–secondary care interface, collaborative or shared care, hospital safety procedures, clinical decision support systems, clinical guidelines, and staff communication and information sharing systems.[20] Changes to organisational systems are often needed when new devices or procedures are put in place.

Five major types of health-care-related technology have been identified, based on the purpose of the technology:[21]

- Diagnostic technology enables treatment or palliative care to take place, by identifying diseases and other conditions.
- Therapeutic technology is used in treating diseases.
- *Enhancing technology* improves human functioning over and above what is needed to cure diseases.
- *Enabling technology, also known as assistive technology,* mitigates the impact of disease or disability. This includes both personalised equipment such as artificial limbs or spectacles, and universal technologies that address environmental or societal issues, such as wheelchair-accessible entrances.
- *Preventative technology* reduces the risk or severity of accidents and other social and environmental sources of disease or injury. This encompasses a wide spectrum of technologies, from hip protectors to airbags to sewage treatment plants.

Diagnostic, therapeutic and enhancing technologies, together with some enabling technologies, such as prostheses, are an integral part of health care. Other enabling technologies, and most preventative technologies, are not closely connected with health care, but may be based on medical knowledge.

One of the key characteristics of new health technologies is the use of information and communication technologies (ICT).[22] This includes electronic health records, digital picture archiving and communication systems (PACS) and pharmaceutical prescribing/dispensing systems;[20] and telemedicine, telehealth and telecare.[23] Telemedicine can be defined as electronically mediated doctor–patient interaction for the purpose of diagnosis or planning case management. Telehealth and telecare are the two main types of systems of remote care.[24] Telehealth is remote surveillance of the health status of patients by clinicians through the collection of data about symptoms or physiological parameters. Telecare monitors lifestyle changes, including potential emergencies, to enable people with social care needs to live independently.

The three new technologies investigated in this study are examples of diagnostic and therapeutic medical devices, all of which need staff to adopt new roles and change the relationship between patients and staff. The therapeutic device is operated by patients themselves in everyday settings, following receipt of suitable training. One of the diagnostic devices is part of a new clinical procedure performed in hospitals, and requires systems to be reorganised. The appropriate setting for the other diagnostic device is disputed, it has been used in various settings: specialist hospitals; general hospitals; and in the community. This last technology uses ICT to produce digital images that are easily transportable across settings.

## The technology adoption process

The process that takes place when an organisation adopts a technology that is new to it (although it may not be new to all organisations) can be regarded as comprising three main stages: initiation, the adoption decision (which may be to reject use of the technology) and implementation.[25] Williams and Dickinson[26] regard the process as a cycle, because initiation, or 'setting the adoption agenda', has as one of its inputs consideration of the existing technology in use within the organisation. They also distinguish implementation of the decision to adopt or procure the technology from use of the technology becoming routine. When the term 'adoption' is used in this report, it refers to the whole of this process, not just to the decision about whether or not to procure.

The adoption process may be influenced by characteristics of the technology itself, such as complexity, scale and cost, which are related to aspects such as the degree to which it may be experimented with on a limited basis (trialability); the degree to which it is perceived as being consistent with existing values, past experiences and needs of the potential adopters (compatibility); and the degree to which the products of the technology are visible to others (observability).[27,28] Characteristics of the organisational context, such as absorptive capacity (an organisation's ability to acquire, assimilate, transform and utilise externally held knowledge),[29] may also be important.

Studies of technology adoption typically take the perspective of an individual organisation. There is also a substantial body of research on the diffusion of innovations, which may be relevant. Diffusion of innovation studies take a macro perspective, looking at the incorporation of an innovation over time into common practice across a whole system or sector of organisations.[30]

See *Chapter 3* for a discussion of underlying theories and conceptual models of the technology adoption process.

## Organisational and policy landscape for technology innovation and adoption in the NHS

### *Innovation*

There are over 3000 companies in the UK whose major business activity involves the development, manufacture or supply of medical devices, or who have significant activity in supplying specialist services to the medical technology sector.[31] Of these companies, 99% are small- or medium-sized enterprises (SMEs) employing <250 people. The market segment with the largest turnover is single-use technology (syringes, dialysis kits, etc.), followed by wound care and management, orthopaedic devices and professional services. Products in some segments have a high rate of product innovation and very short life cycles.

The NHS supports the development of innovative technologies to address health-care needs in a number of ways. The National Innovation Centre, which is part of the NHS Institute for Innovation and Improvement (NHSI) (see *Procurement*), facilitates the identification and development of innovations that should benefit the NHS. Where unmet clinical needs are identified then the National Innovation Centre may run a competition and award a contract for a new innovation to be developed. The Department of Health also runs competitions to find technological and innovative solutions to specific issues through the Small Business Research Initiative, which is particularly suitable for small, medium and early-stage businesses. The resulting innovations are taken to market, but there is no compulsion for NHS organisations to procure them. There are also seven regional NHS Innovation Hubs that help local NHS staff to identify, develop and commercialise innovations.

The National Institute for Health Research (NIHR) has an Invention for Innovation (i4i) programme that funds the development of new technologies and, since 2012, the application of emerging 'disruptive'

medical technologies that have the potential to bring about step change improvements in clinical pathways. The first round of funding focused on cardiovascular disease.

### *Regulation of market access and state health-care benefit coverage*

Medical devices must be assessed to check that they meet European Union (EU)-specified standards before they can receive a licence permitting them to be placed on the market or put into service.[16] Clinical data on safety and performance (ability to achieve the intended purpose) must be supplied for high-risk (category III) devices, but health gain does not have to be demonstrated.[19] Decisions on licensing made by the notified body in one country also apply to other EU countries, but most also have additional national-level regulations which a device must meet if it is to be part of the basket of public health care which may be funded by the state. Data on clinical effectiveness or cost-effectiveness is often required in these national-level HTA processes. Reimbursement rates are decided at a national or subnational level, whereas prices are either decided by manufacturers or limited by the national government.

In the UK, licensing decisions are made by the Medicines and Healthcare products Regulatory Agency (MHRA). The National Horizon Scanning Centre (NHSC) identifies emerging technologies that appear likely to have a significant impact on patients or health services in the near future, including, among other things, medical devices and equipment, diagnostic and predictive tests and procedures, and rehabilitation aids and therapy. The NHSC produces short briefings about the effectiveness of innovative technologies that may be licensed in the next 12–18 months, but these are based on limited information and are not intended to be definitive, making no recommendations about the use of any technology. This work informs more in-depth technology appraisal and assessment programmes conducted by the National Institute for Health and Care Excellence (NICE) and the NIHR, whose HTA programme commissions independent, pragmatic research on the clinical effectiveness and cost-effectiveness of health-care treatments and tests in real-life NHS settings, publishing the results in its own journal series. Most licensed devices are, however, not assessed by NICE or NIHR, but only by local NHS organisations acting independently.

National Institute for Health and Care Excellence has programmes for evaluating diagnostics, medical technologies and interventional procedures. [Until the end of March 2010 the Centre for Evidence-based Purchasing (CEP) produced assessments of medical devices to inform purchasing by NHS organisations. CEP also developed a business case template.] The diagnostics and medical technologies to be assessed are chosen by the Medical Technologies Advisory Committee. The diagnostics assessment programme evaluates the cost-effectiveness of diagnostic technologies that have the potential to improve health outcomes but whose introduction is likely to be associated with an overall increase in cost to the NHS. Such evaluation can be complex because different options for incorporating the technology into the care pathway need to be assessed. The evaluation is conducted by an independent academic group, based on clinical and health economic literature, and appropriate models. Guidance is produced, including recommendations which may concern use or further research. Where costs are likely to reduce or stay the same, diagnostic technologies may be evaluated by the Medical Technologies Evaluation Programme, which also evaluates the cost-effectiveness of medical devices. NICE guidance on diagnostic and medical technologies is not mandatory, so recommended technologies do not have to be funded by local commissioners of services.

In 2012, NICE took responsibility for the evaluation of medical devices and technologies that had previously been managed through the Innovative Technology Adoption Procurement Programme. The Innovative Technology Adoption Procurement Programme invited companies to submit details of innovative medical technologies that could have a high impact on the quality of care, while at the same time reducing costs. Suitable technologies were then added to a list that was circulated to relevant NHS organisations.

National Institute for Health and Care Excellence's assessment of interventional procedures focuses on safety and efficacy, in order to foster safe innovation; it does not assess cost-effectiveness. Procedures are

usually notified to NICE by individual clinicians, then an independent advisory committee decides whether or not to produce guidance. This guidance is usually based on a rapid review of published research evidence and on the comments of specialist advisors and consultees. Recommendations may be for use with normal governance, audit and review arrangements; for use with stricter special arrangements; for use only as part of formal research; or not for use. Although not mandatory, interventional procedures guidance is expected to be followed by the NHS and is enforceable by the Care Quality Commission regulator.

### *Reimbursement of expenditure on new technology*

Payments to service providers for most acute health care in hospitals, but not community services, are specified as national tariffs for particular procedures under the PbR system, based on Healthcare Resource Groups (HRGs).[12] Most tariffs are based on the average cost nationally, uplifted for inflation and adjusted for market forces, with a relatively small number of some tariffs reflecting the cost of best practice.[12]

There are plans to develop tariffs for assistive technologies such as telehealth and telecare. Some high-cost medical devices, as determined annually by a steering group, are excluded from PbR, because they are typically new and innovative, and used in specialist centres rather than evenly across all providers.[32] For excluded devices a local price, which generally should cover the cost of the device, needs to be negotiated between the provider and the commissioner. Commissioners also have flexibility to make additional innovation payments (previously known as pass-through payments[33]), lasting a maximum of 3 years, for new technologies that bring a 'step change' to standard care, taking account of any evidence regarding cost-effectiveness. The guidance refers NHS organisations to the NTAC How to Why to (HTWT) guides to inform their discussions on funding and implementing specific technologies. Changes to care pathways, which may need to accompany new technologies, can be facilitated by 'one stop shop' payments for outpatient clinics involving multidisciplinary or multispecialty teams, or multiple diagnostic tests.[34] Similarly, services can also be 'unbundled' into component elements of care for payment, by agreement between local organisations, provided that this is necessary to achieve policy objectives and that the acute tariff is only unbundled for items commissioned directly from primary care.[35] Reimbursement rates for technologies such as incontinence pads that can be prescribed to NHS patients are specified in the drug tariff for England and Wales, which is updated on a monthly basis.[36] The reimbursement arrangements for medical devices are broadly similar to those in other European countries, with implants and medical aids for inpatient care being included in tariffs, but not certain innovative or expensive technologies, nor the capital costs of technical equipment for professionals.[16]

### *Procurement*

The NHS uses a variety of mechanisms to procure goods and services. There has been an emphasis on trying to realise economies of scale by aggregating procurement of common products across a number of organisations, but also increasingly on strategic procurement to support innovation and adoption. At a national level, the Government Procurement Service procures common products and services, including ICT, across the whole of the public sector. NHS Supply Chain negotiates contracts for a wide variety of products and services at a national level on behalf of the NHS, including the purchase, leasing, maintenance and disposal of capital equipment. Trusts can then, if they wish, order these products from a national catalogue, but they are free to use other means of procurement which may be less costly. Collaborative procurement organisations (hubs) have also been set up by groups of NHS organisations, usually at a regional level.

The NHS Quality, Innovation, Productivity and Prevention (QIPP) programme, which aims to improve the quality of care while making billions of efficiency savings by 2015, includes a procurement workstream. The 2009 National Innovation Procurement Plan[37] envisaged a regional approach to mobilising the procurement function to speed the adoption of innovations. A concordat to encourage the adoption of innovation was also to be agreed between industry and the NHS. Each Strategic Health Authority (SHA) was given a legal duty [since transferred to Clinical Commissioning Groups (CCGs)] to encourage adoption, and a National Innovation Fund was created to support wider diffusion of best practices.

Regional Commercial Support Units were set up to produce a regional innovation plan, and to help tackle barriers to adoption, using the Regional Innovation Fund and the Commissioning for Quality and Innovation (CQUIN) framework. Under CQUIN, a proportion of a provider's contract income is conditional on achieving a package of quality improvements and innovations agreed with the commissioner.

NHS Standards on procurement were published in May 2012,[38] including a leadership standard that innovative technologies and processes are adopted and their benefits measured. The standards also indicate that clinical and non-clinical staff should be engaged with the procurement function, and suggest that establishing a 'clinical product selection committee' is good practice for NHS trusts. Exploring the potential for NHS Supply Chain and the Government Procurement Service to support the procurement of innovation was identified as an area for action. A call for evidence about how procurement might be improved was also issued at this time, with a major concern being how to support the timely diffusion of creative ideas across the NHS.[39] Key stakeholders are represented on the National Procurement Council, which takes the lead on improving practice and developing future strategy.

### *Support for adoption and implementation*

*Innovation, Health and Wealth: Accelerating Adoption and Diffusion in the NHS*, a national strategy for accelerating NHS adoption of innovations that could significantly improve the quality of health and care, was published in December 2011 following a review of evidence submissions by stakeholders.[1] The report highlighted three important stages of innovation: invention, adoption and diffusion. It also identified six barriers to diffusion: poor access to evidence, data and metrics; insufficient recognition and celebration of innovation and innovators; financial levers do not reward innovators and can act as a disincentive to adoption and diffusion; commissioners lack the tools or capability to drive innovation; leadership culture to support innovation is inconsistent or lacking; lack of effective and systematic innovation architecture. The rate of diffusion of an innovation was stated to be influenced by the added value it can provide, how easily it can be implemented, and how visible its impact is. Diffusion was also said to be most effective when top-down, horizontal and bottom-up pressures are all mobilised, including central requirements, regulation, incentives and support; peer influence, collaboration, competition and marketing by suppliers; and patient and public demand, staff enthusiasm and entrepreneurialism. One of the key themes was that the NHS should identify and mandate the adoption of high-impact innovations. The NHS Operating Framework 2012/13 asks NHS organisations to prioritise spread and adoption of innovations, paying due regard to the report.

The NHSI seeks to support innovation and the adoption of best practices across the NHS by building capacity for continuous improvement and change management. In addition to general resources, the NHSI has developed tools for organisations to use to support innovation, and is developing a spread and adoption tool for individual staff to use to identify what they can do to help implementation after an innovation has been adopted. A website to support implementation of the high-impact innovations identified in *Innovation, Health and Wealth: Accelerating Adoption and Diffusion in the NHS*[1] is also being developed. The NHSI has a technology and product innovation directorate, which includes the National Innovation Centre (see *Innovation*). NHSI administers NHS innovation challenge prizes, which provide funding for innovations that have demonstrated a positive impact locally in tackling specific issues, but have not been adopted more widely. The funds support the diffusion of the innovation in the wider field. One of the 2012 issues is improved diagnostic investigation through the adoption of new diagnostic technologies. The NHSI is due to be abolished by April 2013, but some of its functions will transfer to the NHS Commissioning Board, whereas others will be delivered on a commercial basis.

Academic Health Sciences Networks (AHSNs) of local NHS organisations, universities, public health, social care and industry are also to be established from 2012/13 onwards, to facilitate the identification, adoption and spread of innovations of proven cost-effectiveness and best practice.[40] There are expected to be between 12 and 18 AHSNs covering populations of between 3 and 5 million people each with every NHS organisation affiliated with an AHSN. AHSNs will work closely with five already existing Academic Health Science Centres (AHSCs), formal partnerships of NHS trusts and universities which focus more on

researching new innovations that are relevant to the NHS and can be rapidly translated into service improvements.[41] A review is being conducted of NHS- and Department of Health-funded innovation bodies whose functions overlap with AHSNs, with a view to rationalising them.

Various collaborations between the NHS and higher education and research organisations have already been established in order to increase the impact of research on health-care practice. Collaborations for Leadership in Applied Health Research and Care (CLAHRCs) aim to translate applied health research into everyday use in the health service, and to investigate the barriers to evidence-based practice.[42] There are nine of these partnerships between a university and their surrounding NHS organisations. A number of Health Innovation and Education Clusters (HIECs) were set up from 2009 onwards to help put new ideas into practice across the NHS at a local level through training and education, with a particular emphasis on strengthening adoption.[43] HIECs span primary, secondary and tertiary care, and include partners from industry and higher education. Within the NHS, NHS Training for Innovation aims to disseminate training tools for health-care professionals, to support the adoption and correct implementation of new technologies. Projects focus on NHS priorities and identified gaps.

# Chapter 2 Issues with regard to technology adoption in the NHS

## Difficulties in evaluating new technologies

Decisions about whether or not to offer technologies routinely to patients require more information than is provided by the assessments of short-term safety and efficacy for small groups of patients that are required by EU regulations, or even by the more extensive processes undertaken when a technology is assessed by NICE.[44] There is typically uncertainty about associated costs, risks and benefits, and to which population groups they may apply.[45] Furthermore, such estimates can change over time, as technologies may improve in quality, become cheaper, be superseded or be used with a wider range of patients. For example, most of today's coronary artery bypass graft surgery patients would not have been eligible to take part in the clinical trials that established its effectiveness.[46]

Evaluation of radically different technologies is complex because they may be used with a very heterogeneous set of patients, outcomes may depend on practitioner skill levels, significant changes in practice or service reorganisation may be required, and devices with similar functions produced by different manufacturers may not be equally effective (see Tarricone and Drummond,[47] for example). If the technology is expensive, then this means that carrying out a clinical study is risky in terms of the commitment of financial resources.

Where there is a gap in the scientific evidence, clinicians are reliant on expert consensus informed by clinical experience, which may be misleading; in some circumstances product awareness raising by manufacturers or innovators in the form of education, training or awards may then drive uptake.[48] Promoters of telehealth and telecare have used a strategy of downplaying risk and the need for evidence by stressing that the underlying services are essentially the same, with ICT acting only as a facilitator.[23]

'Hard', quantitative evidence on outcomes, particularly from scientific research but also from audits and other data gathering, appears to be more influential than experiential knowledge, which is typically dismissed as anecdotal, with no recognition of the potential usefulness of rigorous qualitative research,[49] again, potentially biasing decisions. New technologies that represent moderate changes are most likely to be problematic, as minor changes should be acceptable by definition, and NICE gives greater scrutiny to major changes.[19]

Once a new technology has been adopted, there is no national system for ensuring that its effectiveness in everyday practice is evaluated. Lourenco *et al.*[19] suggest a framework for staged evaluation of new interventional procedures, which would include mandatory post-market data collection to check clinical effectiveness and cost-effectiveness when the technology is implemented.

## Variable local decision-making processes

Even when there is strong evidence and mandatory NICE guidance has been produced (NICE guidance on interventional procedures is not mandatory), this does not ensure adoption, as the process is left up to individual trusts, who may not have put effective arrangements in place to manage implementation.[50] Furthermore, managers may selectively shape 'evidence' to align it with their own goals and preferred practices.[51]

Some NHS organisations have been found to have more structured processes than others for making decisions about the adoption and implementation of new interventional procedures.[52] Hospital procurement and evaluation committees often play a part in decision-making, with doctors having a key role in defining desirable characteristics of the technology and accompanying support, and in reviewing evidence on costs and benefits,[53] although their involvement is often ad hoc. There is generally a lack of organisational capacity and resources with regard to the purchasing of technologies, with little co-ordination of purchasing among organisations locally, regionally and nationally.[53]

The nature of stakeholder involvement at different stages of the process can affect the decisions made and the outcomes. A study on the adoption of new technologies for infection prevention and control (IPC) by NHS organisations[54] produced a number of pertinent findings. Stakeholder involvement at initiation impacted on which technologies and IPC areas were considered. Those involved in the adoption decision influenced how the technologies were critiqued and what was finally selected. In the organisations where wider consultation occurred early, more diverse approaches to IPC were considered. Support by senior management at the point of decision-making facilitated implementation by mobilising resources and providing increased legitimacy to the initiatives. Involving technology users such as front-line clinical staff from the start of the decision-making process increased their commitment and provided feedback to suppliers, which could be used to help ensure that the devices procured were compatible with working practices and organisational policies. Lack of wider stakeholder engagement in implementation planning was observed to have a negative impact on implementation. Late involvement of the procurement team, due to inexperience or negative perceptions of staff, extended the process.

Lettieri and Masella[55] suggest that when a hospital makes a decision about technology adoption it should consider the expected contribution to value generation and the level of sustainability. Considerations related to value generation include effectiveness, patient or family satisfaction, revenue generation, cost containment and gains in image or reputation, and, in the longer term, creating knowledge by developing new services and health-care technologies and building up new communities of knowledge.[55] Considerations related to sustainability include the degree of self-funding and ratio of fixed to variable costs (economic sustainability); coherence to strategic goals, technology acceptance among physicians and uncertainty in clinical practice (organisational sustainability); technology life cycle and fit with the existing technology portfolio (technological sustainability); and training intensity and coherence of human and physical resources (resource sustainability).[55] Context sustainability issues of coherence to the legal framework and to generally accepted ethics are unlikely to be relevant where a technology has already been approved by national agencies, but will be crucial if the hospital is involved in the development and testing of an emerging technology.[55]

Ong *et al.*[45] suggest that three types of decision-making models are used in NHS hospitals with regard to investing in new technologies: maximising profit is generally favoured by finance directors and managers; maximising competitive advantage is generally favoured by chief executives, marketing directors, research/teaching hospitals and private hospitals; and maximising utility (health outcomes) is generally favoured by clinicians and patients.[45]

The types of information that have been considered in business cases prepared in support of new technologies have included efficacy, alternative treatments, training, cost, potential savings, duration of procedure, safety, benefits, numbers affected, length of stay, pre-operative assessment and cost-effectiveness.[52]

It is widely believed that business cases are only likely to succeed if they show evidence of efficiency or cost savings; demonstrating quality improvements alone will not be sufficient.[45] The criteria for medical device procurement are discussed by Sorenson and Kanavos.[53] Price is the most important criterion because of cost pressures, especially for 'standardisable' products. Quality criteria do, however, tend to be more relevant in specialised or complex surgical areas, where weight is given to the quality of the service as a whole. Other factors often considered include reliability, production capacity/volume, delivery date,

maintenance requirements, and innovative characteristics or technical merit. Therapeutic benefit and cost-effectiveness are sometimes, but less often, considered in purchasing decisions. The emphasis on price may lead to manufacturers focusing on reducing production costs rather than investing in research and development, reducing access to innovative technologies in the long term.

Three main external influences on adoption decisions have been identified in innovators' accounts: (a) economic, such as a focus on cost containment; (b) political, such as the existence of national regulators; and (c) ideological, such as fitting with the 'spirit of the times'.[49]

More formal involvement of physicians in procurement generally might help health considerations to be more prominent in adoption decisions.[53] Centrally planned implementation could also be more efficient and less costly.[45]

## Misaligned financial incentives

Given the importance of costs in adoption decisions (see *Variable local decision-making processes*), there is a need for supportive financial climates.[56] PbR may not be well suited to supporting technology adoption, however. Introducing new technologies always has an initial downward impact on productivity.[57] Additional activities, such as training and clinical pathway redesign, may need to be undertaken, leading to reduced patient throughput, while at the same time raising providers' costs. Yet, under PbR, funding drops whenever activity drops, and there is no allowance for the additional initial costs.

In theory, organisations can address this through the local flexibilities allowed by PbR, such as by linking funding to the actual costs incurred by a particular trust, rather than to the national average cost. There are, however, no centrally published data on the extent to which local PbR flexibilities are being implemented, and the limited evidence that is available suggests that progress is painfully slow. Setting a local price relies on communication and dialogue between providers and commissioners, which may be problematic given the complex and varied factors to be considered, the variability in organisational processes and the conflicts of interest (a higher price suits providers, a lower price suits commissioners) (see *Variable local decision-making processes*). Therefore, any expectations that PbR can operate in its current form without adversely affecting the adoption of new technology look overly optimistic.

Payment by Results may also impede innovation, as there is a trade-off between innovating and productivity.[58] Innovating involves exploration, which raises risk,[59] and a policy climate that relies on financial incentives for activity tends to reduce providers' propensity to take risks.[60]

Diagnostic-related group (DRG) systems organise patients into groups (or categories) on the basis of diagnosis. They began in the USA and are used to reimburse hospitals for the care they provide. In the UK, HRGs are similar to DRGs but they classify patients according to intervention rather than diagnosis. There is also the likelihood that DRG- or HRG-based funding systems may incentivise purchase of technology that yields short-term cost savings, especially if tariffs are not updated sufficiently frequently.[53]

## Barriers within and between sectors, professional groups and organisations

Traditionally, UK health services have operated within secondary, tertiary and primary care sectors, with little interaction between primary care and the others.[61] Lack of trust in the generalised expertise of general practitioners (GPs) has been a barrier to diffusing technology from the hospital sector into primary care.[62] Specialist clinical expertise is the main 'pull' factor, but enthusiasm tends to be for 'high end' technologies rather than the mass 'bargain basement' technologies required for technology transfer into primary care and to support health status monitoring in the community.[63] If technology relies on patient

involvement, there can be additional barriers concerning acceptability, particularly in situations where devices are transmitting data to clinicians. Yet policy expectations are that new diagnostic tools and technological treatments will become available outside of hospital settings, even entering the home as 'near-patient' technologies.[22]

Uniprofessional communities of practice, particularly among clinicians, can provide strong social and cognitive barriers to the spread of innovations:[64]

> *… strong boundaries between professional groups at the micro level of practice slow innovation spread [or flow] … indeed 'flow' is a radically inappropriate image to describe what are erratic, circular, or abrupt processes, which may come to a full stop or go into reverse.*

Even within hospitals, structural complexity and professional rivalries militate against diffusing technology.[65] More than 40 specialties are recognised with little co-ordination between them; indeed, the use of technology has increased rather than reduced medical specialisation.[66] Structural constraints and cultural diversity between specialities[67] foster a situation where technologies do not travel.

Organisational barriers can also limit the appropriate use of technologies; and make supply and demand issues more difficult to negotiate. Fit with the organisational ethos is important, and employees with experience of the technology, or in decision-making positions, can be either a key channel for diffusion or a barrier.[49] Clinicians become risk averse and resistant if they suspect new technology will negatively affect their work with patients or if implementation is difficult,[68] and this is likely to be the case with innovative new technologies, as they will alter the patient pathway and require changes to the roles of professionals involved. Furthermore, the clinical training required to master new technologies raises organisational costs.

Government policy is for technology adoption to be demand led through world-class commissioning,[1] but this is impeded by power imbalances and information asymmetry between commissioners and providers.[69] Progress with developing the NHS commissioning function has been slow, with weaknesses such as passivity still remaining after 20 years, due to shortcomings such as lack of skills and lack of clinical knowledge.[70] The upcoming reorganisation of the NHS, with SHAs and primary care trusts (PCTs) to be abolished and replaced by CCGs and a national commissioning board, is unlikely to help in the short term, and will create new sets of organisational boundaries to be negotiated.

The NHS procurement system has been found to be ineffective, complex and confusing.[71] Centralising medical device procurement is perceived to produce greater cost savings, efficiency and purchasing specialisation, but it may also inhibit competition and emphasise cost rather than quality or value considerations.[53] Several of the procurement hubs have closed, merged or been privatised, while individual trusts continue to have low-volume direct contracts with suppliers, and there may be issues within trusts of 'maverick spending' by individual employees who ignore their organisation's procurement team.[71]

In view of the above barriers, and of the need for social interaction in order to develop tacit knowledge which may be needed to master a new technology, networks and boundary spanning roles are likely to be important in supporting the uptake of new technologies. Champions may be effective in spreading a new technology in their immediate locale, but not necessarily more widely.[72] Change agents have been recommended as a way of overcoming professional boundaries,[56] and clinical networks have been suggested as a means of facilitating uptake across both primary and secondary care.[45]

# Chapter 3 Conceptual grounding and research methodology

## Conceptual models and theories relevant to technology adoption in the NHS

*Chapter 2* highlights the importance to technology adoption in the NHS of financial incentives; the use and generation of evidence during adoption and implementation processes; and boundary spanning across multiple networks and stakeholders. Linear stage models have, however, been the foundation of much research on technology adoption and diffusion. Such models tend to be techno-centric, with the capabilities of the technology being the main enabler of change[73] and determining the social and organisational impacts, such as on governance structures, work routines, productivity and performance.[74]

One strand of the empirical research on technology adoption has focused on information technology (IT). Theories and models that have commonly been used in this research are the Diffusion of Innovation theory, the Technology Acceptance Model, the Theory of Reasoned Action, the Theory of Planned Behaviour and the Technology Organisation and Environment Model.[75] These have been integrated together to produce a conceptual model for the IT innovation adoption process in an organisation.[75] This model is pertinent to our research study because it incorporates the three main stages of technology adoption (initiation, the adoption decision and implementation) which we have used as the basis for our definition of adoption (see *Chapter 1, The technology adoption process*). Initiation is subdivided into awareness of the innovation, forming an attitude of adoption, and developing a proposal for adoption; the adoption decision needs to be backed up by resource allocation for implementation; and implementation requires acquisition of the innovation and user acceptance of it, for actual use to occur. The model also highlights the importance not only of the characteristics of the technology, but also of the organisational context and of technology users.

There is an increasing recognition that the adoption of innovation in health care is a complex process, affected by a variety of factors, but understanding of the interactions is limited.[76] The Normalization Process Model engages with this complexity, focusing on the social relations and processes by which innovations are made workable.[77] A conceptual model of factors affecting the diffusion of innovations in health service delivery and organisation has been developed.[78] This model further elaborates a number of the concepts identified in the model of the previous paragraph, and also maps onto many of the issues that we have highlighted (see *Chapter 2*). Difficulties in evaluating new technologies (see *Chapter 2, Difficulties in evaluation new technologies*) relate to absorptive capacity, which is a key antecedent of user system readiness for innovation. Variable local decision-making processes (see *Chapter 2, Variable local decision-making processes*) correspond to aspects of having a receptive context for change and user system readiness for innovation. Sectoral, organisational and professional barriers (see *Chapter 2, Barriers within and between sectors, professional groups and organisations*) can be addressed by appropriate linkage between users/adopters and innovators, and by suitable communication and influence strategies, of which champions, boundary spanners and change agents are relevant to formal, planned dissemination. The issue of misaligned financial incentives (see *Chapter 2, Misaligned financial incentives*) is less prominent in the model, but is mentioned, and a risk-taking climate is identified as part of a receptive context for change.

These models partially address the criticisms that have been made of viewing technological innovation as a linear, rational process,[79] but we also need to take account of alternative approaches that have been developed. These alternative approaches emphasise the profound uncertainties surrounding technological innovation, highlighting the complexity, political context, broader social network and the social

ramifications of the adoption process (i.e. non-structural determinants such as the micro-politics of the organisational setting, interests, prevalent rhetorics, fads and sociocultural context).[80–83] Our study draws on actor-network theory (ANT) (see *Actor-network theory*),[84,85] boundary work, risk communication and the adaptation of work practices to new technologies (see *Boundary work, risk and the adaption of work practices to new technologies*) because these theories and concepts have been found most efficacious in a large body of previous work on technology adoption (as indicated below).

### *Actor-network theory*

In seminal work, Latour[84,86,87] tracked the complex network of actors required to support new technologies, and the politicised negotiations which accompany their adoption, providing insights as to why innovation could have unintended and undesirable consequences when applied in different settings. However efficacious an innovation may be, its adoption is by no means assured. It enters a professional field characterised by entrenched structures, interests, ideas and aspirations. Success always depends on overcoming resistance and enrolling allies to what can be an ever-shifting support network.

Actor-network theory and the sociology of translation perceive society as constituted by heterogeneous networks of people, technology, materials and objects.[88,89] It focuses on the complex inter-relationships within and between networks of heterogeneous human and non-human 'actors' (individuals, institutions/organisations and technology itself). Both human and non-human elements are considered equally as actors within a network, sometimes being termed as 'actants' in recognition of this (see Callon and Law[85]). ANT particularly explores the process of enrolling social and material elements through which a network is constructed, and the power that emerges from dynamic interplay between networks and actants.[84,85,90,91] Latour[92] suggests that 'contrary to the claims of those who want to hold either the state of technology or that of society constant, it is possible to consider a path of an innovation in which all the actors co-evolve'. Technology, work and organisation are considered to be interwoven and mutually constitutive parts of heterogeneous networks.

Actor-network theory is also concerned with analysing the ways networks become stabilised. Actor-networks that link people, ideas and technologies are not inherently stable and productive but become so through strategic action to define and align the interests of actors in the network. In this view, technological innovation can only be deployed if it is successfully negotiated along a complex adoption pathway, mobilising an actor network. Central to this alignment is how ideas become 'translated' and understood throughout the network. Callon[89] identified four moments of translation which individual actors may pursue, typically in competition with other actors:

1. Problematisation: define a problem and associated solution, which inevitably implies a view about who the key actors are and their associated identities, roles and interests.
2. Interessement: marginalise competing problem–solutions that might be proffered by others, so that the key actors are more likely to accept the roles and alliances allocated to them by the problem–solution being promoted.
3. Enrolment: test and refine the problem–solution through negotiations/transactions as necessary with the key actors, to enable it to succeed in defining and stabilising roles and alliances.
4. Mobilisation: achieve consensus that key actors are valid representatives of their constituent stakeholder groups (there are actually likely to be chains of representatives), so that the problem–solution role configuration/alliance is accepted across the wider network.

At any point, however, actors may not comply with the problem–solution or the identities offered to them, or the commitments made by their 'representatives'. Through the process of translation, ANT emphasises the local and the contingent and how these shape the production of social order. This perspective complements other research which has found that implementation of new technology in hospitals takes place across four stages: enrolment, preparation, trials and reflection.[93]

Several studies have used ANT as an analytical framework to examine technological innovations in health care, resulting in important insights, particularly in relation to exploring the active role of technological innovations in shaping social processes in complex environments. Prout[94] used ANT to analyse how the adoption of the metered dose inhaler can be usefully seen as a means of delegating biomedical work. Hall[95] discussed the transformation of heart disease in the new genetics era by applying ANT to the production of genetic knowledge of one aspect of heart disease – hypertension – within a medical genetics laboratory. Novek[96] examined the introduction and abandonment of a networked drug distribution system in a long-stay care facility in Canada. Cussins[97] drew on ANT to explore the way in which agency and technologies are ordered in an infertility clinic. In a number of studies, Berg[98–102] used ANT to explore the implementation of information systems in health-care organisations. Bloomfield[103] also used ANT ideas to describe the politics of IT to change the NHS. Doolin and McLeod[104] utilised ANT to explore the development and abandonment of an executive information system in a hospital. Elsewhere, Bossen[105] illustrates the implementation of an electronic medication plan in three hospitals in a county in Denmark. Cresswell *et al.*[106] discussed the role of ANT in understanding the implementation of IT developments in health care. Nicolini[107] found ideas from the sociology of translation helpful in describing the emergence of telemonitoring in Northern Italy.

Despite its wide use in technology studies, ANT has been widely criticised for assuming that human and non-human actors can be treated as equivalent.[104,108–111] We found evidence that clinical technologies (non-human actors) do act (see *Chapters 5–7*), but they do not act strategically and so are not equivalent to human actors. In the light of this, it is suggested that the application of ANT is most useful if combined with other theoretical lenses that can help to address some of its shortcomings.[88,112–115] This study is therefore supplemented by complementary work on boundary spanning work,[116,117] ideas underpinning risk communication[60] and research on the adaptation of work practices to new technologies.[118–121] All of these conceptual tools highlight the strategic role of human actors and, therefore, complement ANT, as indicated in the following section.

### *Boundary work, risk and the adaptation of work practices to new technologies*

Boundary work[122,123] refers to the instances in which boundaries, demarcations or other divisions between bodies or communities of knowledge become established, expanded, reinforced or undermined. Initially developed to help understand the boundaries of bodies of knowledge, for example between science and non-science, the notion of boundary work has since been applied in many disciplines, including government policy and science,[124,125] the sociology of professions,[126,127] organisation studies[128] and social studies of science.[123,129] A number of studies have focused on the changing constitution of boundaries to protect professional identities and control of resources.[123,129] Others have sought to explore the role of boundary spanning actors and their strategies to manage cross-boundary connections across different disciplines and domains of practice.[130,131] Elsewhere, studies have focused on boundary objects[132–134] and their capacity to facilitate the translation of meaning across different communities of knowledge or practice.[135,136]

In the context of innovation, boundary work plays a key role in the adoption of ideas, practices or technologies within and across organisational settings.[137] Here the relevant communities of practice and associated barriers might relate to differences such as professional commitments (technology providers vs. clinicians; primary vs. secondary care) and levels of technical knowledge.[137] Organisational barriers within and between sectors can limit the appropriate use of technologies; they can also make supply and demand issues more difficult to negotiate. Conversely, boundary work and boundary spanning roles have the potential to facilitate technology transfer along the adoption pathway.

As highlighted in *Chapter 2*, *Difficulties in evaluating new technologies*, *Misaligned financial incentives* and *Barriers within and between sectors, professional groups and organisations*, various factors are likely to contribute to new technology adoption being perceived as risky. The benefits of adopting a new technology are usually uncertain because of the lack of robust evidence. In addition, the PbR system increases the probability that adopting a new technology will have adverse financial consequences for a

service provider. Furthermore, some stakeholders may resist the implementation of new technology because they perceive that it will have negative social, political or organisational consequences for them (e.g. disruption to services), at least in the short term, and sometimes in the long term too (e.g. deskilling). Where new knowledge can be codified, it can be advantageous to be a late rather than an early adopter, building on the codification undertaken by earlier adopters in order to achieve greater rates of performance improvement.[138] Risk perception can be an important factor influencing new technology adoption. If the outcome of an innovation is uncertain and is perceived as risky by powerful actors in the organisation then it is less likely to be adopted.[78] The intentions of top managers of medium-sized US hospitals to adopt new technology have been found to be related to their propensity to take risks.[139] Risk communication across boundaries is important because clinical research indicates that risk perceptions are mediated through communication; and training in constructive dialogue can improve decision-making in the presence of risk.[140,141]

Recent research on the adaptation of work practices to new technologies has identified ongoing opportunities for innovation by users through the local customisation and configuration of technologies and systems in situated practice.[118–121] This activity is required to render technologies appropriable by users as 'working systems' in a specific context. This position recognises that the trajectory of innovation does not reflect its technical advantage in terms of any inherent capabilities and characteristics (i.e. innovation as a fixed product), but rather recognises the appropriation of innovation by user communities within 'local practices, purposes and culture'.[73] As such, new technology will be still further shaped and reconfigured during innovation and diffusion; what has been called 'innofusion'.[142] The appropriation of technology in this way involves both 'practical efforts to make technology work' and action to 'create meanings' that enable a technology to become embedded in the identity and culture of user communities.[73]

## Methodology

The research questions (see *Chapter 1*) investigate issues that are underexplored and, often, context dependent. Therefore we relied, in the main, on a qualitative methodology, although for one of the technologies this was supplemented by a survey which we analysed quantitatively. In effect the clinical technologies were case studies. Our core interests were focused on how intraorganisational and policy implementation barriers were negotiated (or not) but we found that other aspects impinged in significant ways. For example, the extent to which the clinical efficacy and utility of the technology was accepted as proven, the nature of the interface between primary, secondary and tertiary care, and relationships with technology producers. Hence, we looked at the technologies holistically, so the case study methodology was highly relevant.[143,144]

The case studies focused on three clinical technologies: insulin pump therapy (IPT), breast lymph node assay (BLNA) and ultrawide field retinal imaging (UFRI). This focused approach was agreed in consultation with NTAC. We decided that, within the time constraint of 3 years, intensive research would be more productive than a more superficial approach over all the technologies that NTAC supported (around 15 at the time the study commenced). The three technologies identified in discussions with NTAC were those which presented the most complex and puzzling problems with regard to adoption and implementation. NTAC themselves had been unable to understand the reasons why these three technologies were underadopted despite their intensive project work. Current government policy for improving technology adoption, as expressed in *Innovation, Health and Wealth: Accelerating Adoption and Diffusion in the NHS*,[1] takes a selective approach by supporting only six technologies. Similarly, in focusing on three technologies, we undertook an intensive research design. We describe the adoption issues for the three technologies in detail next.

### Technology and site selection

Insulin pump therapy is not a new technology. It has been accepted as efficacious for about 30 years, but adoption and implementation rates have been consistently higher in the USA and Europe than in the UK.[145] Despite working with several UK sites, NTAC still found the underadoption of IPT in the UK perplexing. BLNA is a new technique requiring considerable training for surgeons and histopathologists and presenting complex adoption and implementation issues. It necessitates diagnosis of lymph node tissue while the patient is anaesthetised in theatre, thus requiring either a pathology laboratory in close proximity or histopathologists to work within theatre. As it is unknown which patients will require the diagnostic before their operation, the technique introduces considerable uncertainty into theatre lists and the work schedules of the histopathologists involved. NTAC works with secondary care but UFRI is a technology that may be more efficacious employed in primary or tertiary care settings. Therefore, for UFRI, there are problematic issues over knowledge exchange and service integration along the patient pathway between primary, secondary and tertiary care.

Shortly before the research began the NTAC UFRI project was closed down. Of the three trusts selected as implementation sites, two pulled out before their projects started and the third decided not to proceed after the technology had been demonstrated by the producer at the trust concerned. In consultation with NTAC, we decided, nevertheless, to go ahead with researching the adoption and implementation issues at the third secondary care site and also at tertiary centres (TCs) where the UFRI was in use. Subsequently, we identified a 'high street' optometrist (HSO) who was working with the technology; this site was also included.

For IPT and BLNA, secondary care site selection was in consultation with NTAC. For both technologies we selected a mentor site (MS) (a trust implementation site which had been closely involved with NTAC over the development of the online HTWT guide and which takes queries from other trusts over the technology); two further implementation sites; and one site which was implementing the technology without NTAC's assistance, and which may, therefore, be reliant on the HTWT guide.

### Plan of investigation

A senior team member led and co-ordinated each of the clinical technology case studies. For UFRI this was Professor Sue Llewellyn; for IPT, Dr Gill Harvey; and for BLNA, Professor Rob Procter. We adopted a part-sequential, part-overlapping approach, so that, if in the initial stages any complex generic problems were encountered, these could be resolved before we started the next case study. As we thought the UFRI case study may pose more access problems (owing to the NTAC project closing down), we commenced this first to give more time to investigate where and how UFRI was being used. The IPT case started next, and lastly the BLNA case. The majority of the interviews were conducted by two team members – the relevant senior team lead and the research associate, Dr Gregory Maniatopoulos. This ensured that the research associate was supported when interviewing senior clinicians (or managers) and enabled cross-checking of interpretations of what was said. Most interviews lasted about 60–90 minutes and they almost always took place at the office of the interviewee (a few took place at Manchester Business School, Manchester, UK). Awaydays and other relevant meetings or events were also usually attended by two team members.

To guide the research and debate issues an advisory board was formed, which met biannually. The members were Professor Andrew Webster (academic expert on clinical technologies); Professor Carl May (academic expert on clinical technologies); Ms Lesley Jordan (patient representative for IPT); Dr Heather Waterman (Professor of Nursing and Ophthalmology); Ms Sally Chisholm (NTAC Chief Executive); Dr Stuart Eglin (Director of Research and Development, NHS North West); and Dr Martin Gibson (Consultant Diabetologist and Network Director of Salford Diabetes). Despite our best efforts we were unable to identify a patient representative for breast cancer who was available to join the advisory board.

Ethical approval processes influenced the timing of our investigations. The application for central NHS approval began before the research started; this was agreed and completed soon after. Approvals from

individual trust research and development committees were also started in a timely manner. However, some did take rather a long time, impacting on the sequencing of our research at individual trust sites.

### *Research design*

Our study took place from October 2009 to October 2012. The research was conducted in three stages. At *stage one* we undertook a *scoping exercise*. We familiarised ourselves with the extant literature. For the three technologies, we attended NTAC awaydays (whole-day meetings for all NTAC project stakeholders) to meet the staff involved and ascertain the stage of development of the project, the main barriers and enablers and the stakeholder networks. We also piloted the semistructured interview schedule at two sites and made some consequent changes.

*Stage two* encompassed the *primary data collection.* We conducted 73 semistructured interviews: 16 across 9 organisations for UFRI; 23 across 4 organisations for IPT; and 34 across 6 organisations for BLNA. For IPT and BLNA, we were guided by NTAC over the selection of interviewees (i.e. the key clinicians and managers in the implementation project networks). For UFRI, outside of the trust site, which had proceeded with a successful application to be an NTAC implementation site but then subsequently withdrew, the industry producer informed us of TC sites where the technology was in use. All interviews were taped and then transcribed by a reputable company. We also collected background documentary evidence including the sources relating to NTAC's decisions to accept particular trusts as implementation sites; notes of meetings at the trusts and at awaydays (sometimes, where possible, these were taped and transcribed); and internal trust or commissioner documents on technical or funding issues regarding the three technologies. Originally, we had intended to the map the networks required to negotiate adoption and implementation issues. However, at the scoping stage, we realised that this had already been accomplished by NTAC, in the sense that they had involved all stakeholders, both internal (including clinicians, managers and nurses) and external (including commissioners and patient representatives). The networks were sometimes looser than we had anticipated as, outside of the core clinical working relationships, contacts between, for example clinicians and commissioners, were rather sporadic. The networks were, however, unambiguous, established and encompassed all relevant stakeholders. Hence, there was no necessity for us to uncover and map them nor did we need to suggest further network members. It should be noted, however, that these established networks were much less strategic and much more operational than we had anticipated. We had envisaged strategic discussion between interested clinicians, trust managers and the PCT over technology adoption to identify patient benefit, predicted productivity gains, if any, and impact on costs, before the technology was taken up in practice. These were the networks that we intended to map as they expanded if the technology was successfully embedded. Such networks did not occur or, rather, we found only one instance of this, paradoxically for UFRI where adoption and implementation did not progress. Rather than a strategic approach to adoption, clinical champions began to use a technology in practice and, if they found it efficacious, they investigated possible funding sources (e.g. 'soft' research money, charitable monies or possibly a business case to trust management or the PCT). In the early stages of adoption there was no network or, rather, the 'network' was a small number of clinicians who worked together on a day-to-day basis. NTAC did ensure that contact was made with other relevant stakeholders (e.g. commissioners and patient representatives), but the focus was on operational rather than strategic concerns. The implementing group (or, in some cases, individual clinician) was highly localised within the particular trust.

As mentioned earlier, IPT is the technology with the longest history of use, yet uptake is still disappointing. During the final year of our research, a member of our advisory board made us aware of a network of clinicians established by NHS Diabetes in May 2012 in recognition that 'provision of insulin pump therapy in England is patchy, with few centres providing more than 25 pump starts per year'.[146] (For further details of the network and how clinicians engage with it, see www.diabetes.nhs.uk/networks/insulin_pump_network/?#.) This survey was not planned in our protocol but we decided that it was worthwhile to take advantage of the opportunity presented to gather quantitative data. The network consists of approximately 320 clinicians at UK trusts who are actively engaged (i.e. are a part of a network with a specific interest in IPT which enables the sharing of good practice) in trying to increase

their IPT uptake for all patients who meet the criteria. At stage two we undertook an IPT survey of these individuals (i.e. the entire population). The survey was not incentivised. For reasons of data list confidentiality, our survey was distributed by the network manager on our behalf. The online questionnaire is included in *Appendix 3*, as is the informational e-mail we sent to all group members inviting them to participate. The survey was distributed through the support group lead in May 2012, soon after the network was established. Ninety-one responses were received, a response rate of 28% (91/320). We did not undertake any follow-ups or a survey of those clinicians who had not joined the network because we were in the last few months of our research, and this would have required significant additional work.

There is an active patient information and support group for IPT. The lead for this group was an advisory board member. Through this route we had access to anonymised e-mails from patients who had contacted the group. We analysed these e-mail data for themes. This work was also undertaken at stage two.

*Stage three* covered the *role of NTAC within the network*. We interviewed the NTAC chief executive (both the person who occupied this role at the beginning of the project and the one who took over) and the two NTAC project implementation managers who ran the technologies we investigated. We also included questions about the role of NTAC and the HTWT guides in our interviews at the trusts and PCTs at stage two. To explore whether or not NTAC's expertise can be codified in the HTWT guides we filmed five staff and one service user advocate using the IPT HTWT guide and two staff using the BLNA guide (because the NTAC UFRI project was closed down, there was no guide). These participants had agreed to be filmed at interview (not all interviewees did agree, hence the numbers were restricted). These video sessions were conducted at the participants' place of work. The audiovisual equipment was supplied by Manchester Business School. Participants were instructed to navigate the online guide at their own chosen speed and in their own chosen way while articulating their thoughts on both the content of the site and the use of navigation. A team researcher was present throughout to answer any questions and prompt if necessary. A professional audiovisual technician undertook the filming and, subsequently, edited the output before making it available to the research team.

### Research methods

This was a mixed-methods study, using a variety of methods to investigate different aspects of technology adoption and to increase validity through triangulation.[147] Semistructured interviews were used to explore technology adoption in the case study sites in relation to the broad themes of our conceptual model, but without imposing specific prior categorisations.[148] Participant and non-participant observation of awaydays, meetings and an IPT parliamentary briefing event organised by a public relations company hired by NTAC helped us to understand and take account of the organisational context.[149] Document analysis[150] provided written confirmation of issues, particularly regarding technical and funding information. A survey of trusts committed to increasing IPT uptake provided quantitative information regarding the extent to which NTAC had made an impact across the wider NHS outside of the case study sites.[151] Analysis of patient concerns over IPT, as expressed in e-mails to a patient support group, provided a contrasting perspective to that of NHS staff. Finally, a 'think out loud' method captured participants' responses to the NTAC HTWT website pages on video, in order to provide insights into users' cognitive processes as they made use of the HTWT guide and to highlight any problems.[152] A summary of all the data collected is provided in *Table 1*.

In the proposal we anticipated some diary work. We did not ask participants to record their situated responses to the ongoing flow of network interactions in diaries, however, as this proved neither feasible nor sensible. As discussed above, the networks around the technologies were well established by NTAC. Therefore, network interactions either were an aspect of day-to-day clinical work or took place at formal meetings such as awaydays or other organised events, which we could observe.

However, on reflection, we did think the networks that NTAC established were somewhat limited. This is understandable in view of NTAC's small size and resource base but the restricted nature of the networks did preclude some possibilities. Contact between the research sites and the Department of Health, for example, was negligible. Such contact may have facilitated funding variation for new technologies under

**TABLE 1** Summary of all data collected for the study

| | Case study | | | |
|---|---|---|---|---|
| | UFRI | IPT | BLNA | Whole study |
| Period of investigation | December 2009–July 2012 | July 2010–July 2012 | October 2010–July 2012 | December 2009–July 2012 |
| Organisations from which interviewees were drawn | | | | |
| Implementation sites | 0 | 2 | 3 | 5 |
| MSs | 0 | 1 | 1 | 2 |
| Non-/withdrawn implementation sites | 1 | 1 | 0 | 2 |
| Other NHS trusts | 4 | 0 | 0 | 4 |
| Commissioners | 1 | 0 | 1 | 2 |
| NTAC | 1 | 0 | 0 | 1 |
| Other organisations | 3 | 0 | 1 | 4 |
| Total | 10 | 4 | 6 | 20 |
| Interviewees | | | | |
| Implementation sites | 0 | 12 | 27 | 39 |
| MSs | 0 | 4 | 5 | 9 |
| Non-/withdrawn implementation sites | 7 | 7 | 0 | 14 |
| Other NHS trusts | 4 | 0 | 0 | 4 |
| Commissioners | 1 | 0 | 1 | 2 |
| NTAC | 1 | 0 | 0 | 4[a] |
| Other organisations | 4 | 0 | 1 | 5 |
| Total | 17 | 23 | 34 | 77[a] |
| Observations | | | | |
| Meetings/awaydays | | | | 8 |
| HTWT guide use (videos) | | | | 8 |
| Survey (IPT) | | | | |
| **Time period** | **Population** | **Respondents** | **Response rate** | |
| May 2012–July 2012 | 320 | 91 | 28% | |

a Includes three NTAC staff whose interviews were not limited to a particular case study.

PbR. Also, the network interaction between providers and commissioners was operational and ad hoc rather than strategic.

### *Data analysis*

In keeping with the qualitative nature of much of the data, the process of analysis for the semistructured transcribed interviews, notes of meetings, awaydays and other events and documents was iterative. This process was structured using thematic analysis.[153] Core themes were identified inductively within each setting, after which we verified or qualified them by making further comparisons between individual participants and sites and technologies.[154] The objective of this process of iteration and comparison was to develop robust thematic categories that enable understanding of the conditions that either facilitate or hinder technology adoption and implementation; some explanatory themes were generic across the three technologies but others were technology specific (as evidenced in *Chapters 5–7*).

Most of the data from the IPT online survey were categorical or ordinal. Free-text comments were listed and checked to see if they indicated that a particular response should be excluded from the analysis, and for triangulation with the themes emerging from the case studies. The quantitative data were analysed by producing some simple descriptive statistics (frequency charts and tables) for each question, using the functionality provided by the Qualtrics software (2012; Qualtrics Labs, Inc., Utah, USA) used to design the survey. Cross-tabulations of all pairs of questions were also produced, and a chi-squared statistic calculated for each one, in order to see if there appeared to be any relationship between the data items.

The videos of staff attempting to use the HTWT guides on the NTAC website were first processed electronically to take the form of a split-screen presentation. This presentation showed the computer display as seen by the user as he or she navigated the website, including mouse movements, with a small cut-out in the corner of the screen showing a synchronised video of the user, with his or her facial expressions and arm gestures visible. A researcher viewed each video, observing the path taken through the website by the user and his or her accompanying body language. When the user spoke, summary notes were made, including some verbatim quotes where these appeared to capture an important point. Key themes from across all of the user sessions were then identified.

# Chapter 4 The role of NHS Technology Adoption Centre

## Introduction

NHS Technology Adoption Centre was established in 2007 to directly address the problem of underutilisation of clinical technologies in the NHS. At the time of this research, NTAC was funded by the Department of Health, NHS Institute and NHS South West. NTAC is a small organisation, with, as of February 2013, personnel consisting of a chief executive, three technology implementation managers (who run the projects at the trusts), a data manager, a performance and operations manager and an administrator.[155] This modest size means that NTAC cannot support all the trusts that apply for assistance with technology adoption.

The NTAC approach is to work at selected trusts with, for the technology concerned, all relevant stakeholder groups to resolve adoption barriers, understand adoption enablers and embed the technology in day-to-day working practices. This modus operandi is clearly understood by NTAC as an implementation project rather than a pilot or trial. The outcome of NTAC's learning at selected sites (usually three or four for any particular technology) is distilled into an online HTWT guide. These guides are intended to give trusts that were not selected as implementation sites, along with others who may wish to implement the technology concerned in the future, sufficient information to enable them to undertake an implementation project without NTAC's active involvement.

The NTAC process starts by identifying suitable technologies through putting out a call to industry. The criteria for selection are indications that the technology will result in a step-change in health-care provision; the technology should already have some, albeit suboptimal, uptake in the NHS; the technology should be in an area of national policy priority; the technology should be in a clinical area of major focus; and, preferably, the technology should have undergone some form of appraisal. Overall, an NTAC implementation project is focused on an underadopted technology that, nevertheless, has a substantial evidence base for clinical efficacy and utility, including system-wide benefits.

For all clinical technologies, with respect to 'substantial evidence base', NTAC's remit is somewhat problematic. Under European directives, clinical technologies are classified as 'devices' (see also *Chapter 1, Types of clinical technology*). In the UK, EU directives are implemented by the MHRA. Under this regulatory regime, manufacturers are required only to demonstrate that the technology is safe and fit for purpose; unlike pharmaceuticals, they do not have to undertake clinical trials to demonstrate clinical efficacy (see Cohen and Billingsley[156] for a comparison between the EU requirements for devices and the more stringent US regulations). Although, compared with the USA, the somewhat looser EU requirements can be criticised, the knowledge and skills to benefit fully from new technologies are often acquired only after adoption into clinical practice.[19] On the other hand, it should be noted that informal evaluation through practice does not always work well. Some technologies enter the market and become firmly embedded in routine practice, but later are found to be ineffective or harmful.[19] Thus, the clinical efficacy and utility of many technologies becomes apparent only over time, as the learning curve plays out.[157]

NHS Technology Adoption Centre's approach of working with trusts on implementation does fit with the profile of clinical technologies. As the efficacy and utility of many technologies only becomes fully apparent over time, an implementation project which takes place over an extended period of time and engages all stakeholders to maximise learning should give the best chance of revealing clinical efficacy and utility. After an NTAC technology implementation manager has completed a due diligence report to ensure that the technology meets the criteria for selection (outlined above), NTAC puts out a call to trusts to invite their

interest in being an implementation site for the technology concerned. The criteria for site selection are the overall thoughtfulness and credibility of the application in terms of patient benefit; capacity of the trust to implement the technology; and perception of adoption and implementation barriers. The preferred NTAC model is to work with three trusts out of those who apply, each with differing implementation barriers in order to maximise the on-site implementation learning that feeds through to the HTWT guides.

## Theoretical framework

We argue that technology implementation can be understood through ANT. The clinical efficacy (or not) of any technology is not the only determinant of successful adoption and implementation. A key aspect is whether or not the technology becomes embedded in a network and whether or not that network is powerful. An actor network does not have any a priori form, it is not confined to sectors, organisations or even projects, it traces associations as new events and interventions occur.[158] A network, according to ANT, does not only associate human agents;[159] non-human agents (actants) are also mobilised and assembled.[88] In ANT terms, a clinical technology is an actant. Such actants can acquire agency in one of two ways: either actions that were carried out by humans are delegated to them or the actant displaces a human (or humans) in the network.[160] Hence, a basic tenet of ANT is that social phenomena cannot be analysed through human intentions and actions alone; non-human entities also have agency and, hence, participate in the networks that determine social outcomes.[161] These non-human actants have material form; they may be technologies but they may also be concrete practices.[162]

Our analysis of NTAC, through ANT, begins by arguing that NTAC's starting point for its implementation projects was somewhat underspecified (i.e. implementation projects were defined more by what they were *not* than what they were). NTAC's first chief executive recognised that if an implementation project began as a 'pilot study', the agency attached to the practice of 'pilot study' would seriously diminish the possibility of successful implementation. So the starting point was that an implementation project was *not* a pilot.

The remainder of this chapter addresses the following issues: NTAC's approach to the implementation of clinical technologies; their views on implementation barriers and enablers; and their intentions and experiences with the HTWT guides. We then cover the answers to our survey questions on the HTWT guides and participants' responses to the video method of capturing their online guide experience and conclude with a short summary of the main issues raised in this chapter. (The interview evidence on the HTWT IPT and BLNA guides is presented in *Chapters 6* and *7*.) In the sections below we include data from the first NTAC chief executive, the second NTAC chief executive, the project implementation manager for the IPT and BLNA cases (the same person undertook both) and, briefly, the implementation manager for the UFRI case (this was terminated before we started the research, as described under *Chapter 3*, *Methodology*).

## What is the NHS Technology Adoption Centre approach to the implementation of clinical technologies?

In ANT terms, the pilot study – as a practice – is an actant. The agency of a 'pilot study' in negating 'total buy-in' and, thus, rendering technology implementation optional in a network was understood by NTAC's first chief executive. She was determined that the trusts accepted that their project was truly about implementation rather than a pilot which could be terminated.

> *My aversion to pilots was well known and very well documented; having been involved in them. If we genuinely wanted to understand the barriers we would never do that without getting total buy in from the trust we were going to work with.*
>
> *First NTAC chief executive*

The end point of NTAC's implementation was also clear. It was agreed from the beginning that learning from each of the projects would be embedded in a HTWT guide for the benefit of future trusts who wished to adopt and implement the particular technology. Enrolment is a key stage in the ANT sociology of translation.[89,163] The agency of the HTWT guide in enrolling and, therefore, enabling technology implementation was assumed by NTAC.

> *The idea behind the guide was to showcase the success of the sites we'd worked with and that would enable other trusts … Here's your business case. Here's your costing model. Here's your evidence. It [the HTWT guide] brought everything together, basically.*
>
> *Implementation manager: IPT, BLNA*

The NTAC approach was absolutely clear in one other respect – it had a 'bottom-up' agenda. It worked at the trusts on implementation. It was not a national organisation that issued dictates from above.

> *I could write how I think we should overcome the barrier of tariff, ok? And I could be absolutely correct … But if I can't back it up with an example, then people will say, 'This is an academic exercise.'… Some national organisation, they don't live in the real world. That was the whole idea of working with the trusts.*
>
> *Implementation manager: IPT, BLNA*

Between the start (not a pilot study) and end points (the production of a HTWT guide) there was no structured process; no set 'model' for clinical technology implementation at the trusts. In part, this stemmed from a lack of central direction from the Department of Health.

> *I think, initially, I inherited a business plan which had been developed by a consultant to look at NTAC – but it was extremely outdated. And quite honestly I don't feel at that point the Department of Health was clear itself on what it saw NTAC doing.*
>
> *First NTAC chief executive*

The NTAC approach laid considerable responsibility on the project implementation managers, who pursued their own operational plans within the overall remit of 'implementation'. The first chief executive compared this to an early-stage company.

> *I was only one step ahead of the project manager. That's what happens in an early stage company. And we were an early stage company to all intents and purposes. I was reasonably comfortable with that scenario.*
>
> *First NTAC chief executive*

In consequence, the NTAC project managers had considerable autonomy in setting the implementation agenda.

> *There was no model. There was no laid out plan of how to do it … She [the chief executive] wanted people who could come in, who were experienced, who had enough seniority to push this change forward. To be in that environment, you needed to have some initiative of your own … [the chief executive] said to me, 'I don't care how you do it … Here's your budget. Now go away' … I had a blank piece of paper.*
>
> *Implementation manager: IPT, BLNA*

In ANT terms, however, the 'blank piece of paper' perspective is somewhat naive as human agency always depends on the power of the network within which it is embedded; an actor is an effect generated by many interacting material and non-material entities.[164] A hospital trust is a world that is 'pre-figured'.[165] NTAC staff will have to engage with and transform pre-existing networks around, for example, the patient pathway to ensure technology implementation. The 'blank piece of paper' is, actually, already inscribed.

This inscription does not preclude a technology from transforming the pre-existing networks. Indeed, NTAC staff showed awareness of this. The actors, material artefacts and practices that make up any network are continuously being reconfigured through new events and interventions.[164,166] Indeed, clinicians and managers are not always aware of current practices.

> *Let me tell you something. Nine times out of ten, people do not know how patients are moving through the system now, so never mind with a piece of technology that completely changes it.*
>
> *Implementation manager: IPT, BLNA*

Implementation projects enabled 'stakeholder engagement', which, although NTAC staff did not use ANT language, proceeded through Callon's 'four stages of translation'.[89] The first stage is 'problematization', where a problem is defined as shared across disparate sets of actors but one set of actors privileges itself in stating how the problem can be solved. In the case of NTAC, the problem is how a technology can be implemented through stakeholder engagement. In the quote below, an NTAC project manager positions himself as able to begin to solve the problem as he, as opposed to the clinicians, is aware of all the relevant stakeholders:

> *The first thing to do is identify the team. And it's not just the clinical personnel. I mean, clinicians often think that the whole world revolves just around their clinical colleagues, but what about the finance manager? What about the commissioner? What about the procurement? Clinicians say 'What's procurement?' You say, 'Your supply department.' Then they say, 'Who are they?'. Well actually, they're the ones that are going to get this technology in, so you'd better find out who they are.*
>
> *Implementation manager: IPT, BLNA*

Along with stakeholder engagement, the NTAC staff declared that they possessed the requisite project management skills. Callon's second stage is 'interessement',[89] where privileged actors propose roles for other sets of actors and gain their commitment to certain courses of action. At this stage, NTAC staff state that clinicians are unable to 'work through project plans', thereby appropriating for themselves the roles of project managers. The project implementation managers also proposed certain goals such as awaydays and a 'tight time frame'.

> *They're clinicians by day, they're clinicians by night too, they don't have the luxury of being able to work through project plans … It's up to us to do that … And within that, I would say we need to incorporate things like the awaydays, but plan for it at the beginning … [And] there needs to be a tight timeframe.*
>
> *Implementation manager: IPT, BLNA*

Callon's third stage is 'enrolment',[89] where the proposed roles and courses of action are consolidated. In the next quote the NTAC project manager consolidates the local network team through connecting them to 'subgroups' (or other networks). He then assigns further specific roles and responsibilities to these subgroups while positioning the role of the local clinical champion, with whom NTAC communicates, as 'overseeing' all the subgroups.

> *It's not just about having an overarching team locally, but subgroups as well to give ownership of certain elements … Ok, the nursing staff, they're the ones who'll see these patients, ultimately. Yes, it's a pathology test, but you're the ones that follow them through. Go and design the pathway. Bring it back in six weeks and we can talk about it together. You go and speak to the accountant … you need to go and draw up the specification for procurement. Let's have a procurement subgroup. And that's what the clinical champion needs to oversee, all of those subgroups.*
>
> *Implementation manager: IPT, BLNA*

The fourth stage is the 'mobilization of allies', where further actors are drawn into the networks which can communicate with each other through the 'immutable mobiles' (e.g. procurement specifications) established at the enrolment stage.[89] After enrolment, through clinicians and managers, NTAC has produced new patient 'pathways', 'specifications for procurement' and 'business cases'. These are the immutable mobiles that enable communication at a distance and act as 'obligatory points of passage' for the separate, but now interconnected, networks in pathology, physiotherapy, psychotherapy, PCT commissioning and patient representation.

> *You need your clinicians from all the areas the technology impacts on. So, for example, even though it's a technology that sits in pathology, it impacts on theatres, on the wards, on nuclear medicine, on pathology, the nursing team, physiotherapy, psychotherapy. All those departments need to be included and, equally, the decision-makers, the people who will sign off the business cases, the trust accountant, the PCT commissioner, and also, where possible, a patient representative.*
>
> *Implementation manager: IPT, BLNA*

Overall, NTAC respondents stressed the implementation gaps that NTAC fills in its 'downstream' and 'practical' approach to innovation in the NHS.

> *NTAC is the only organisation in the NHS looking at the downstream delivery of technology. There's so much about introducing technologies – you know, having a relationship between innovation and research and development. But NTAC is really looking downstream where something isn't working; why a particular technology is not being taken up by the NHS.*
>
> *Implementation manager: UFRI*

> *I do think there is an ethos of us being a practical organisation rather than a theoretical one.*
>
> *Second NTAC chief executive*

Where a technology is not 'being taken up' into a network, NTAC works in a practical way 'on the ground' through the translation stages outlined above to try to ensure that networks are created and sustained around the technologies concerned.

The next section explores NTAC's views, based on its experience, on what the generic implementation barriers are in the trusts and how these can be overcome.

## NHS Technology Adoption Centre's views on implementation barriers and enablers

The first chief executive revealed how her thinking on barriers had shifted, making reference to 'pathways', 'clinical utility' and 'systems impact'. Technology adoption and implementation always take place within the context of pre-existing networks. The concepts of 'clinical utility' and 'systems impact' capture aspects of this issue. There will be a pathway along which patients move, and the pre-existing networks of clinicians and practices will have shaped how this patient pathway has developed. These networks cannot be easily recast to enable technology to enter, so much has to be done to make the trusts become comfortable with the new ways of working, which involves creating new networks.

> *My view was it must be the NHS's fault. It's difficult, it's reactionary, it isn't interested in technology. But as we started to talk to clinicians and managers we realised what issues there are in bringing devices and diagnostics through the system as compared to drugs … we started to think about the pathways, clinical utility, all the really serious questions that needed answering to make a trust comfortable that they should bring a new technology in.*
>
> *First NTAC chief executive*

We argue above that four stages of translation need to occur for a technology to be implemented into networks. At the first stage, NTAC has to convince the clinicians of the technology's clinical utility. This means more than scientifically showing that the technology is clinically efficacious; it also implies that it has clinical utility (i.e. the technology can work in the context of clinicians' perceptions about how the care of patients should take place).[167] Clinical experience has considerable weight in judgements on clinical utility.[168] Hence, translation may not occur, may be only partly achieved or may be delayed through successive implementation cycles. Therefore, management is crucial in enabling change.

> *So it's about making the change possible, changing the pathway, changing their [clinicians'] mindsets and – and this is a word that we use a lot now – enabling.*
>
> *Implementation manager: IPT, BLNA*

The first NTAC chief executive emphasised how the technology can act on systems to 'change the whole dynamic'. In doing so she expresses the central ANT insight – that *any(thing)* that changes the dynamics of practice is an actor.[88]

> *The technology can suddenly change the whole dynamic of the procedure.*
>
> *First NTAC chief executive*

The second chief executive continued in this vein, through pointing out the necessity for new ways of working and developing new networks around the technology. Law[164] uses the concept of 'punctionalization' to express the idea that the networks which embed technologies are often taken for granted. Clinicians become aware of the networks that generate effects (such as clinical pathways, training and the tariff) only when they need to be changed to incorporate a new technology.

> *You're helping organisations to re-design their clinical pathways, training implications and tariff consequences and all of those sorts of things … It's a step-wise process of [the clinicians] saying, 'What do we need to change or how do we need to change the way we're working to use this [technology]'?*
>
> *Second NTAC chief executive*

For change to work, the ANT perspective draws attention to local agency. There may be powerful elite actors who agree to change, but there also have to be agents 'at the coal face' who implement change. All these actors (elite and 'coal face') have to be connected for change to happen.[162] This NTAC project manager points out the importance of consultants *and* nurses *and* the relationships between them.

> *I've learnt a hell of a lot about how to navigate around the importance of relationships, the importance of who is engaged, ownership. Yes, you need to pamper the consultant's ego, but it's the nurse on the ground that ends up doing it.*
>
> *Implementation manager: IPT, BLNA*

Within these network relationships, PbR constitutes a possible major barrier to technology implementation because any new technology disrupts established networks, requires the formation of new networks and, therefore, at least in the short term, reduces patient throughput and, in consequence, reduces income under PbR.

NTAC staff identified PbR and associated tariffs as a major barrier to technology adoption and implementation.

> *I have witnessed these barriers. I have witnessed finance managers saying, 'Well, we're going to lose income, so we can't bring in this test.'*
>
> *Implementation manager: IPT, BLNA*

The first chief executive explained that if NICE made a technology mandatory it could also create an interim HRG code. She noted, however, that this could take time to materialise.

> *NICE puts out a guideline for a new piece of technology which may not have a tariff. It tells the trust they have to adopt it but it doesn't tell them how they're going to get paid for doing that. What I was trying to push NICE to do is create an interim HRG code for the moment that the guidance is given so that a trust can start using it and develop some reference costings around it. But that's going to take time coming through and NICE, of course, is going to have to change.*
>
> *First NTAC chief executive*

The second chief executive noted that the lack of a tariff for many technologies meant that the trusts incurred costs that were not reimbursed.

> *Lack of tariff for these technologies means that the trust are shelling out on disposables and sometimes on capital but it's not picked up at all [in the tariff] so again it can be a real cost thing for all of them.*
>
> *Second NTAC chief executive*

The HTWT guides were intended to enable the trusts to overcome these barriers. The next section explores NTAC's intentions and experiences with these guides.

## NHS Technology Adoption Centre's intentions and experiences with the How to Why to guides

As mentioned earlier, the HTWT guides were the end point of the NTAC process, as understood in its agreement with its funding organisations.

> *NTAC was originally funded to produce the guides as well as work with a small number of organisations.*
>
> *Second NTAC chief executive*

One intention was that the HTWT guides would be a 'roadmap'. In ANT terms, NTAC intended the guides to be an 'obligatory passage point':[87]

> *They can follow a very clear road map of what needs to be done at each stage; [for example] If you look at the guide for breast lymph node the documentation there will include a patient consent form to have all of that done in one surgery. So they haven't got to think of any of the things … all the pieces of the jigsaw – it's all there ready to download. So the one thing they do need to do is to get the right people round the table. And we even tell them who the right people are.*
>
> *First NTAC chief executive*

Another intention was that the guides were 'tools', particularly as templates for business cases to trust management.

> *The 'How to Why to' guide gives them the tools. So if they need to make a case to their manager, there are costing models, there is the core basis of a business case there, so they're not starting completely from scratch.*
>
> *Second NTAC chief executive*

A key neglected issue, however, was the need to publicise the guides so that clinicians and managers in the trusts knew they were available.

> *So the notion of dissemination was the production of the guides, which would be a resource to the NHS. What wasn't given any thought was how the guides were publicised and used.*
>
> *Second NTAC chief executive*

Later, NTAC hired an agency to publicise the guides and, hopefully, enable knowledge diffusion about the technology concerned throughout the NHS.

> *Yes, publicise the guides, in the hope that there'd be an element of diffusion that way. We've gone through a professional communications agency.*
>
> *Second NTAC chief executive*

However, on reflection, it was felt that there was a certain naivety in thinking that the guides would work to promote diffusion of the technologies.

> *So the methodology was … to share learning with the NHS via the How To guide. And I suppose, looking back, it was naive, but the vision was then that people would pick up those guides and adoption would filter through.*
>
> *Implementation manager: IPT, BLNA*

In the next section we explore the extent to which clinicians, managers and patient representatives did use the guides.

## Clinicians' and managers' views on and experiences with the How to Why to guides

We report here, first, on responses to the IPT survey of a network of English clinicians who were actively engaged in trying to increase the uptake of IPT at their trusts. We asked these clinicians about their awareness and use of the HTWT guides. Second, we summarise participants' filmed comments on both content and ease of navigation when actually using the online guides.

The results of the survey are as follows. First, we asked simply if respondents (all clinicians) were aware of NTAC; 54% were. Of those who were aware of NTAC, 63% were aware of the guides. We asked next about use of the guides. There were four predefined categories of 'use': a business case to your trust to develop your service; a business case to your commissioners to develop your service; an information resource; and to contact other trusts with experience of developing their service. Respondents were asked to tick all that apply. Of those who had used the guides, 96% saw it as an information resource, 13% used it for developing a business case to the trust, 13% for developing a business case to commissioners and only 8% to contact other trusts. Finally, we asked about the helpfulness of the guide: 54% were neutral; 20% found the guide somewhat helpful; 14% thought it extremely helpful; and 11% somewhat unhelpful.

A summary of comments (from clinicians and managers) while navigating the HTWT online follows. First, we discuss the main issues raised on the written content. Participants said that there is lots of useful information for managers and clinicians, if they can find the site and persevere in looking through it, although it can be quite hard 'to see the wood for the trees'. Others found the site 'generally unengaging' and thought that the content generally emphasises the complexity of the process and is a long read. This was thought to be a danger because the content emphasises a time-consuming technical process, but political issues might be more important for implementation success, for example getting people on side at an early stage and identifying champions. The guide provides information aimed at commissioners, which is a strong point. The language is accessible for clinicians but may not be for patients.

Second, the main issues raised were on navigation and presentation. The website may need to provide different 'ways in' for different stakeholders with different purposes and interests. The layout of the guide assumes that people will read the executive summary first, but this may not be the case. The links to NICE guidance, in particular, are helpful. More visual interest would help, for example images of different insulin pump models might engage the attention not just of patients but of other stakeholders too. The slowness of some pages to load could be a barrier to people's use of the site.

## Summary

Although NTAC personnel did not think they worked to a clinical implementation 'model', we concluded that their approach built new networks through the ANT sociology of translation.[89] Once new networks were in place they adopted project management techniques to maintain momentum and ensure an end date. Individual project managers had considerable autonomy. Although this often worked well, in the case of UFRI, the management of this project may have been an aspect of its early close-down (see this case study). In terms of key implementation barriers, NTAC identified PbR and the tariff. Implementation was enabled through actively ensuring stakeholder engagement and paying particular attention to rethinking patient pathways. Intensive work did generate results in accelerating technology implementation at particular trusts but NTAC's reliance on the HTWT guides to ensure wider diffusion throughout the NHS was not very successful. In particular, clinicians rarely used the guides to build a business case to trust management and commissioners, despite NTAC concentrating efforts on the business case aspect. The issue of how best to ensure the wider diffusion of efficacious clinical technologies throughout the NHS is discussed at some length in *Chapter 8*.

# Chapter 5 Ultrawide field retinal imaging case study

## Introduction

This case study focuses on a clinical technology used to detect and diagnose peripheral pathology in the retina. UFRI technology was regarded by NTAC as proven, clinically efficacious but underadopted. Our initial understanding from NTAC was that the main adoption barrier was lack of clarity over where the technology was best situated (e.g. in primary, secondary or tertiary care, or all of these). NTAC staff also commented on the possible problems engendered by implementing in secondary care when most benefit may accrue within primary care (i.e. staff in secondary care may feel somewhat exploited). These issues were evident in the case study but there were other significant barriers. There was ambiguity over not only *where* the technology is best deployed but also *how* it should be used. There was also uncertainty over *what* UFRI should be used for, i.e. the target medical conditions for which it is most efficacious. These ambiguities and uncertainties are still not fully resolved and remain barriers to the adoption of UFRI into clinical practice, as further discussed in relation to our empirical evidence below.

The UFRI case study was undertaken first. At the time this research was funded, one trust had successfully applied for NTAC's support to implement UFRI. However, by the time the research began, this trust had withdrawn from the NTAC project and was not using UFRI. Brief details of this site are given in the following section.

### *Withdrawn implementation site*

The site is a foundation trust with a good working relationship with the PCT. The trust's business development manager had secured agreement from the PCT to fund the UFRI technology. This was mentioned in the application to NTAC to become an implementation site. We obtained notes of a meeting held on 15 September 2008 between the business development manager, the lead ophthalmologist and a representative from the PCT. In these notes it was stated that 'The trust's ophthalmology service has experience of trialling community-based triage (conventional technology), where an ophthalmologist is sometimes available at optometrist locations'. Also:

> *The lead clinician is keen to cut unnecessary referrals from primary care in order to optimise use of clinicians' time and to increase throughput of patients with a genuine need to see a consultant at secondary care. Eyemap would be used in secondary care to provide a second level of filter (using technician staff rather than doctors) at the point of entry in the secondary care pathway.*

It was also recorded that:

> *The lead clinician believes that the deployment of Eyemap in care pathways would, because of the upstream filtering that it provides, actually result in the identification of a greater number of people requiring secondary care. Consequently, he would not expect to see a reduction in trust income from deploying Eyemap, conversely to some beliefs.*

At this point in the notes there was a comment from NTAC that this possible loss of income would be further evaluated during the project.

The site looked to be suitable in several respects: a history of good relationships with the PCT; a commitment from the PCT to fund the technology; previous experience with working across the primary–secondary care interface; and a carefully thought out application to NTAC.

In consequence, their subsequent withdrawal looked surprising. We decided to research why this trust [referred to as the withdrawn implementation site (WIS) in the empirical sections] had pulled out, but we experienced some difficulties. There are eight consultant ophthalmologists. (Four of these are at a neighbouring site as ophthalmology services are shared across two hospitals.) Of these eight, seven agreed to be interviewed (one of these declined to be recorded). In general, these interviews did not prove very informative. The lead clinician declined an interview despite both email and telephone requests. This was disappointing as he had been highly instrumental in the application and the later decision to withdraw. We also requested minutes of the meetings that had taken place between representatives at the trust and the PCT when the decision to withdraw was taken. Both the trust and the PCT told us that their minutes were lost. As this seemed an unfortunate coincidence, we put in a Freedom of Information request but this only elicited a result that the minutes could not be found.

Aside from this WIS, we also gathered evidence from sites where the technology was being used in tertiary care and by optometrists, as further described in *Chapter 3, Methodology*. *Table 2* gives details.

NHS Technology Adoption Centre's remit developed over the 3-year timeline of our research. At the time of the UFRI case study, NTAC's aims are best described as follows:

> *[NTAC] was established with the overall remit of improving the uptake of under adopted innovative technology in the NHS. This is achieved by NTAC working with NHS trusts to implement preselected under adopted but proven technologies into standard care and using this as a learning opportunity to discover how the barriers to the adoption of the technology can be overcome.*[45]

With respect to whether or not UFRI is proven, to date, the technology has not been subject to a UK NICE technology appraisal nor is one under development at the present time (see NICE[169]). However, UFRI was cleared by the US Food and Drug Administration (FDA) in 1999 and has undergone further evaluation (including clinical trials) since the technology entered the US market in 2000. The availability of this evidence did not always ensure that clinicians and hospital managers accepted that UFRI was 'proven'. These perceptions over 'lack of proof' were also a barrier to the adoption of the technology.

**TABLE 2** Interviewees for the UFRI case study

| Organisation | Number of interviewees | Interviewee role/job title |
|---|---|---|
| HSO | 1 | Optometrist |
| NICE | 2 | Director and associate director, implementation support |
| NTAC | 1 | UFRI implementation manager |
| EYE | 1 | EYE owner |
| PCT | 1 | Commissioning lead |
| TC1 | 1 | Consultant ophthalmologist |
| TC2 | 1 | Consultant ophthalmologist |
| TC3 | 1 | Consultant ophthalmologist/ocular oncologist |
| TC4 | 1 | Consultant ophthalmologist |
| WIS | 7 | Business development manager |
| | | Consultant ophthalmologist (×6) |
| Total | 17 | |

EYE, Eyeco Plc.

The structure of this chapter is as follows: first, there is a brief overview of the technology to explain its features, purpose and clinical utility within the patient pathway. (The clinical research cited merely gives selected indicative work; within the limits of this non-clinical research there are no claims to comprehensiveness.) Next, the empirical evidence gathered for the UFRI case study is presented and discussed. The empirical sections cover the extent to which the technology is proven; its clinical utility (how the technology is best deployed and for what target conditions); where the device should be situated; and the impact of PbR on adoption. Throughout this chapter the abbreviation UFRI is used to indicate the generic description of the technology as UFRI, Eyemap refers to the images the technology generates and Eyeco is the manufacturer.

## Ultrawide field retinal imaging

The technology is a scanning laser device which provides wide-field (up to 200°) retinal images;[170,171] this wide field view captures approximately 82.5% of the surface of the retina.[172] Colour images can be obtained without dilating the pupils, corneal contact or high degrees of illumination.[173] These digital images can then be viewed on screen.[174] Once in the computer, images 'can be magnified, enhanced, annotated, printer, stored or emailed'.[173] The peripheral retina can indicate evidence of pathology in many ocular conditions.[172] Hence, Eyemap images enable identification of peripheral eye abnormalities and should aid the earlier detection of retinal pathologies.

The patient pathway for the detection and diagnosis of eye disease is rather complex and somewhat uncertain. In the UK, eye disease is often first detected by ophthalmic opticians (or optometrists) on the high street. Dispensing opticians are only usually licensed to provide glasses based in current prescriptions. In contrast, optometrists are qualified to carry out eye examinations in primary care and, hence, are in a position to assess the health of the eye. If an optometrist detects eye disease they may refer the patient to an ophthalmologist in secondary care; sometimes this referral will be via the patients' GPs. Ophthalmologists are medically qualified, specialising in the diagnosis and treatment of eye pathologies and practising eye surgery. Many eye conditions that result in sight loss are painless (e.g. cataract, open-angle glaucoma, age-related macular degeneration and retinal detachment).[175] Thus, for many serious eye conditions, pain will not prompt individuals to seek medical attention; 39% of the UK population do not have their eyes examined on a regular basis.[176] It is calculated that 50% of sight loss is avoidable through early detection and intervention.[176] Detection of disease in the retinal periphery has been problematic: 'Until recently, the retinal periphery went largely unimaged, mainly because until now there existed no easy way to image it'.[177]

In current practice the gold standard for examination of the retinal periphery, 'includes a dilated retinal examination by an ophthalmologist with indirect ophthalmosocopy and often requires scleral depression'.[172] [Scleral depression is a technique which depresses the wall of the eye inwards (see Albert *et al.*[178]).] Dilation of the eye is time-consuming, uncomfortable and results in blurring of vision, which lasts for several hours; it is inconvenient for patients and, as compared with undilated examinations, results in reduced patient throughput for practitioners. In the UK, the gold standard examination is somewhat rare in practice, usually in primary care an eye examination by an optometrist is done without dilation; dilation of the pupil is normally only performed by an ophthalmologist within secondary care.[179] Even when performed in secondary care, only 10–12% of the retina can be viewed at any one time,[180] and no digital image is available for later review. These issues suggest that an Eyemap digital image (which can be done without dilation) may replace, duplicate or add to traditional methods. Among studies to date, there is currently a lack of consensus over these possibilities. One study evaluating the clinical efficacy of UFRI suggests that it 'does not replace the dilated fundus [interior surface of the eye including the retina] examination, but is a powerful tool in patient education, photo-documentation, and retinal and systemic disease detection and prevention in conjunction with our current instrumentation'.[173] On the other hand, Nath *et al.*[181] found that UFRI detected some lesions missed during a dilated examination, and concluded that UFRI 'appears to be additive (as well as duplicative) to the dilated exam'.

Friberg *et al.*[182] tested UFRI as a screening device for specific eye diseases and concluded that its use is viable and merits further research. Mayers[173] suggests that the use of UFRI 'aids in the early detection of a variety of eye conditions [including] diabetic retinopathy, various forms of macular degeneration, posterior vitreous detachment, retinal holes and tears, hypertension, some types of leukaemia, and retinal detachment'. Silva *et al.*[183] concluded that non-dilated UFRI images compare favourably with both traditional dilated photography and a dilated clinical examination in determining diabetic retinopathy and diabetic macular oedema (watery fluid collection in the macula, the area of the retina where vision is keenest); they noted, however, that the UFRI images were obtained more rapidly, thus enhancing the efficiency of the screening process. Witmer and Kiss[172] suggest that the full utility of UFRI will only be revealed over time.

The issue of whether, and in what circumstances, UFRI could replace, or add to, the gold standard examination was a matter of some debate among the participants in this study, as discussed further below.

## Is Eyemap a proven technology?

The ways that 'proof' is best obtained is contested in clinical practice. In the light of this situation, along with the issue that regulators do not require clinical technologies to be subject to clinical trials, the question of whether or not Eyemap is 'proven' is considered in broad terms in this section. Debates around evidence in scientific journals are discussed along with those of awareness and 'take-up'. Aside from proof, clinicians' perceptions of Eyemap's utility in clinical practice is discussed in the next section.

Specialists in TCs are aware of publications and evidence for UFRI, but, as highlighted later, this knowledge tends to remain confined to specialist centres.

> *There are countless publications out there about the device and its usability.*
>
> *Consultant ophthalmologist, TC2*

In the UK, these specialists are instrumental as clinical 'champions' and in raising awareness of the technology.

> *I got interested in the use of Eyemap at least five years ago. I'm always looking for new technologies that can help me understand better retinal diseases … And that was, for me, the main drive to try to get an Eyemap into the X Eye Hospital. I succeeded with it and we had the first Eyemap of the current generation in the NHS.*
>
> *Consultant ophthalmologist, TC4*

One specialist indicated that, in the UK, advertising and awareness of the technology was still not high.

> *I think the whole advertisement and awareness of the Eyemap and what it's capable of has not been very high. As I say, I only came across it by chance. Now, that may be due to resources in the company or it may be just the way they've targeted telling people about it, but a lot of how we find out about things in reality is going to meetings or speaking to colleagues who've got something and you hear about it.*
>
> *Consultant ophthalmologist, TC1*

Therefore, as may be expected, some respondents stress that interest is more intense in other countries where take-up is higher than in the UK, especially among optometrists.

> *Germany uses Eyeco a lot, Italy uses Eyeco a lot, there are over 4,000 machines in the States … So, the UK is lagging very, very far behind … I would say about 90 per cent of the machines are optometrist, most optometrists in the States have one.*
>
> *Consultant ophthalmologist, TC2*

> *I'm off to Norway to lecture in October. I'm going to be lecturing to more optometrists in one room than I can lecture to in 24 road shows in this country. Because they're so keen to embrace that modern technology and they can see the benefit for the patient. And you know, in the States, it's huge.*
>
> *Optometrist, HSO*

When assessing whether or not clinicians accept that there is supporting evidence for a technology, one relevant issue is that some sites follow the lead set by others. In the implementation site that withdrew, the next respondent comments that his trust adopts technologies *after* they have been assessed elsewhere.

> *We get technologies that are already known to most people. We know that it's useful, we know where it will be used, and we know about some of the research that has been done.*
>
> *Consultant ophthalmologist 4, WIS*

Late adopters of technology are less likely to have unrealistic expectations over what a technology can deliver. Knowledge about UFRI and what it can deliver is being generated in tertiary care. Therefore, outside of this somewhat rarefied realm, expectations were sometimes unrealistic and, therefore, not met. The business development manager in WIS articulates a discourse of unfulfilled expectations around 'undilated pupils'.

> *The key technical aspect, which the equipment had promised, was that examinations could be done with an undilated pupil. Basically [under current procedures] there is a 45 minute wait for drops to be activated [to dilate the pupil] and not being able to drive, you've ruined your day … But what we found was that all this technology could do is add another test to the current patient pathway instead of replacing it with another pathway.*
>
> *Business development manager, WIS*

In addition, a tertiary specialist confirms that the expectations of 'some people' exceeded what the technology could accomplish.

> *Some people expected never to have to do a clinical exam again, the gold standard is clinical examination, I'm sorry but there's no way of getting away from actually looking at the patient. There is no imaging out there that will give you all the answers without looking and talking to the patient. So I think the hype around it rightly or wrongly was much more than it could deliver.*
>
> *Consultant ophthalmologist, TC2*

So if the technology could not replace the 'gold standard' clinical examination, what was its clinical utility?

## Clinical utility: what are the benefits for practice?

The first point is that, based on his experience, one tertiary specialist thought that Eyemap *could* sometimes substitute for clinical examination.

> *It does actually help the diagnosis more than I thought … we're beginning to find that just looking at the photograph is often better than the doctor looking in. Or at least, it's just as reliable and, in many ways, more reliable … it does lead, I think, to safer practice. You're missing less pathology just due to taking a wide field.*
>
> *Consultant ophthalmologist, TC1*

In contrast, in WIS, based on arguments that retinal pathology usually occurs in the centre, one ophthalmologist declared that Eyemap was 'just not useful' in clinical practice:

> *It's just not useful in clinical practice. The majority of problems do not occur in the far periphery, the majority of problems occur in the centre. The majority of meaningful problems, of problems that are going to affect your vision, are easily imaged by our current systems, OCT [optical coherence tomography] and other technologies.*
>
> *Consultant ophthalmologist 7, WIS*

This difference of opinion may, at least partially, be explained by the differential type of conditions that are treated in secondary and tertiary care. Obviously, tertiary care specialists treat rarer and more complex pathologies. Therefore, the benefits of the technology may accrue differently across the two settings. On the other hand, the tertiary specialist quoted below identifies 'efficiency' as his first priority; this seems to be a generic advantage. Indeed, as explained above, expectations of 'time savings' through being able to carry out undilated examinations was a prime reason for WIS considering Eyemap in the first instance. In the view of this tertiary specialist, efficiency is increased due to the rapidity of image collection with the Eyemap.

> *I realised if I wanted to record a diabetic, I could do an [Eyemap] photograph in thirty seconds, if I sent them for a colour photograph on the standard fundus [interior surface of the eye] cameras it'd take fifteen minutes/half an hour for the same result … in terms of why we have the Eyemap: firstly, it's efficiency … it's much quicker.*
>
> *Consultant ophthalmologist, TC1*

Despite the comment above from the secondary care ophthalmologist who maintains that since most pathology is situated centrally there is little benefit in imaging the periphery, there is some consensus among the tertiary specialists that the fundamental benefit of Eyemap is the capacity to image the periphery of the retina.

> *If you do a very, very thorough imaging of the back of the eye peripherally you cover up to about 70 to 80 degrees and Eyeco covers to 200 degrees. So a lot of the stuff that goes on, on the very periphery of the eye you won't see with any other imaging techniques.*
>
> *Consultant ophthalmologist, TC2*

> *The main benefit of this camera, over anything else, is wide field imaging.*
>
> *Consultant ophthalmologist, TC1*

> *I think there's no better system on the market at present to visualise the peripheral retinal vasculature, to the point that, if I could, I would have all my patients who need an angiogram imaged with an Eyeco. Obviously, we can't because we've got only one system. But if I could, that is the only system I would use.*
>
> *Consultant ophthalmologist, TC4*

The optometrist conveyed a specific narrative on patient benefit.

> *I couldn't work without an Eyemap as there's two thirds of the retina that I've not looked at. I've got enough patients now who are asymptomatic, one's a contact lens patient, very high prescription [and, therefore, at increased risk for retinal detachment]. And there right in the periphery was a huge tear … had she [just] gone to bed that night, she would have probably woken up the next morning and had very little vision in that eye.*
>
> *Optometrist, HSO*

As mentioned earlier, there is uncertainty over where and how Eyemap is best used and for what target medical conditions. With the presence of uncertainty in all of these key areas, assessment in specialist TCs over time appears to be required. Indeed, this specialist queried the validity of any assessment of Eyemap in secondary care.

> *You know, if you go to [WIS] and they don't like it, well frankly, who's heard of them from an eye department point of view? It's not like a big teaching hospital, is it?'*
>
> *Consultant ophthalmologist, TC1*

One aspect where there was some consensus over clinical utility was for patient education.

### Patient education and communication

As Eyemap produces digital images, another aspect of its clinical utility is for patient education and communication. Aside from the diagnostic potential of Eyemap, in specialist ophthalmic oncology, Eyemap images support effective communication with patients; education was cited as a major clinical benefit.

> *Here [specialist oncology] most patients see worse when we're finished than when they come. I really have to communicate with them to tell them [for example] the tumour is right next to the nerve, you can see there in the Eyemap picture, the chance of losing vision is 50:50. When they're convinced with these pictures, then they're happy with the results. Otherwise they'll be suing us, they'll be complaining.*
>
> *Consultant ophthalmologist/ocular oncologist, TC3*

On the other hand, another specialist argued that photographic documentation can increase litigation as it creates an historical database which could be used by patients' lawyers to demonstrate that pathology existed even if it was not detected.

> *We've now got photograph proof of pretty much everything. So if someone wants to go and sue you, you've created like a massive pool of evidence. If you haven't acted upon it then you can be asked why.*
>
> *Consultant ophthalmologist, TC2*

From the patient's perspective, however, the possibility of using Eyemap as a means of supporting legitimate complaints and litigation is a benefit; such issues highlight that Eyemap can do more than diagnose.

### Advancing knowledge and learning through Eyemap

Two of the tertiary specialists commented that Eyemap enables them to advance their knowledge of ophthalmological conditions.

> *But then I started imaging these patients [with macular juxtafoveal telangiectasia, a blinding condition of the retina] with Eyemap and I've started seeing that some of these patients present large areas of capillary non-perfusion in their periphery that have not been described before.*

> *So clearly, we are seeing things with the Eyemap that we were not aware of. It's a completely new way of looking at the condition.*
>
> *Consultant ophthalmologist, TC4*

> *We've found, using the wide field Eyemap fluorescein, we're actually detecting stuff that we didn't know was there … that we didn't actually see clinically.*
>
> *Consultant ophthalmologist, TC1*

Indeed, although Eyemap is described as a diagnostic technology, on occasion UFRI technology gives information that even specialist ophthalmologists cannot assimilate into their existing knowledge base.

> *Scientifically we don't really understand how the central vision and the peripheral vision play together in terms of disease progression in many of the diseases. So because we don't understand it, it's like, oh, let's not worry about it … In diabetes it's different because we sort of understand it.*
>
> *Consultant ophthalmologist, TC2*

These knowledge deficits render the interpretation of Eyemap images difficult.

> *It is a very, very steep learning curve to learn how to interpret Eyemap images … because people don't routinely look at a large number of eyes on the periphery, they're not used to what is normal and what is not normal that far out in the eye.*
>
> *Consultant ophthalmologist, TC2*

Knowledge deficits are a problem for the use of Eyemaps. In consequence, Eyeco appointed a US specialist to act as an advisor on interpretation. He was reported by the Eyeco producer as commenting:

> *My god, these people in Britain, they send me the most Mickey Mouse cases; don't they know anything?*
>
> *US specialist, cited by owner, Eyeco Plc*

This statement seems to support the limited uptake and use of Eyemap in the UK as compared with the USA, discussed at the beginning of this section.

The above is evidence of the clinical utility of Eyemap for research and for patients with rare or complex conditions in tertiary care, but, along with efficiency, through increased patient throughput, what would be the benefits to secondary and primary care? The next section addresses the issue of where the technology is best situated.

## Where should ultrawide field retinal imaging be situated and what should it be used for?

As discussed above, WIS decided against going ahead with the technology. The technology was demonstrated by Eyeco at the trust but there was no subsequent in situ trial to determine clinical utility. The lead clinician made the decision not to continue with the NTAC implementation project after the demonstration. Although he declined to be interviewed, he summarised his objections in an e-mail. These were as follows: the equipment is bulky; maintenance is expensive; it is more suitable for optometrists; the demonstration did not impress; no evidence that the image resolution is better than their current digital photography; they were led to believe that pupil dilation was not necessary but the images are better with dilation (e-mail communication, 24 March 2010). At interview, the seven other consultants who had been present at the demonstration also commented. As the demonstration preceded the interview by more than 1 year, their recollection of events was quite poor. Their remarks are briefly summarised as follows. One consultant did not remember the demonstration at all and was unsure whether or not he was involved in

the decision. Three consultants thought that the main view was that the technology was not needed at a district general hospital. Of these three, one was of the opinion that it was better situated in primary care and one that it was of most benefit in tertiary care. Two felt that the resolution was not good enough. The seventh (who declined to be recorded) thought that the decision had actually been made by the lead clinician (who declined to be interviewed).

Yet, as discussed in the previous section, after working with the technology, the tertiary specialists thought the technology conferred several benefits. This first consultant thought that a case could be made on the grounds of efficiency. He commented further on its potential use in secondary care:

> *In terms of a hospital [secondary care], I think it has a big role in the eye department, but it hasn't been taken up widely, and why is that? I think it's partly people not considering the full benefit of it. It's partly the change in need in ophthalmology. Everybody's looking at ways of being more efficient. I think this is one way.*
>
> *Consultant ophthalmologist, TC1*

And he was specific about its use 'in the clinic', as opposed to research.

> *What do we use it for in the clinic … Increasingly, we would take photographs of diabetics, people with any retinal vascular problem … Inflammatory conditions, again, it's very useful to take an Eyemap picture. Choroidal nevus [pigmented area] or, you know, suspicious tumours or something, again, an Eyemap will probably go out further.*
>
> *Consultant ophthalmologist, TC1*

But another tertiary specialist commented that the secondary care clinic in his hospital had not adopted Eyemap.

> *If I don't have the Eyemap the other cameras are very inferior … but in the rest of the hospital people seem to be quite happy with the cameras they have.*
>
> *Consultant ophthalmologist/ocular oncologist, TC1*

At stake here is the issue that the research findings on Eyemap and clinical experience of Eyemap in tertiary care are not being disseminated to secondary care. There is no formal conduit for this to happen. Without a national policy to ensure diffusion of clinical technologies to appropriate sectoral sites, it seems, at the moment, that the clinical utility of Eyemap will not be exploited outside of tertiary care.

### *Should Eyemap be used in primary care?*

Aside from its ad hoc use by optometrists, what is the potential utility of Eyemap in primary care? This tertiary specialist comments on the detection of eye pathology at an earlier stage.

> *I think that [in optometry] Eyemap will enhance the detection of tumours … if the tumour is picked up earlier, instead of having a big operation there would be a much smaller operation to put a radioactive disc behind the eye. A much greater chance of keeping vision. And not just detection of tumours, tumours are very rare, 600 in all of Britain every year have a melanoma, that's all. But for diabetic retinopathy, for seeing haemorrhages at the back of the eye and for macular degeneration and for all sorts of things. So to have a camera like this in an optometry practice I believe would be useful.*
>
> *Consultant ophthalmologist/ocular oncologist, TC3*

This view, from a tertiary specialist, of the benefits of UFRI in optometry contrasts with that of one of the ophthalmologists at WIS, who remarked that:

> *In primary care at the opticians, it's a gimmicky thing, yes, you produce a photograph. But it may produce more false referrals. It may pick up a bit of pigmentation which causes unnecessary alarm and unnecessary referral.*
>
> *Consultant ophthalmologist 7, WIS*

One UK optometrist conveyed the following narrative over his use of Eyemap:

> *I had somebody with a retinal detachment that was diagnosed [in secondary care] as retinoschisis, which is a split in the retina rather than a detachment. And I actually wrote in the letter [to the secondary care ophthalmologist] a whole series of reasons why it wasn't a schisis and why it was a detachment. [But] The patient was discharged with a schisis. And the next day he lost completely the vision in that eye and was rushed to [a specialist hospital] to be treated. I can understand an ophthalmologist saying if you hadn't had that technology you might not have even seen the schisis, let alone the detachment. I feel threatened by you having that equipment because you can see things that I might miss. Therefore, I'd rather you didn't use that equipment because that leaves me still at the top of the tree.*
>
> *Optometrist, HSO*

Traditionally, in the UK, optometrists can only detect. Only ophthalmologists can diagnose. Diagnosis is non-routine work. If, with the arrival of UFRI, optometrists begin to diagnose then the status of ophthalomology, as a preserve of the non-routine work of diagnosis, is threatened. This dynamic seems to underlie the turf war over the proposal for a primary care eye clinic:

> *We were advocating a central clinic whereby if an optometrist saw a patient whom he would normally refer to the [secondary care] eye clinic, you would actually refer them to that [central] primary care eye clinic. And it would be staffed by optometrists. The idea was that if you go into 10 different optical practices you will have 10 different types of equipment. If you standardised it then your output from each optometrist should be the same, so you could actually look at that; you could audit the results, you could target training if you had a weak optometrist. But it was stamped upon by the ophthalmologist of the day.*
>
> *Optometrist, HSO*

If patients were referred to a primary eye care clinic, staffed by optometrists who could diagnose, this should, over time, reduce the number of ophthalmology referrals to secondary care. This would reduce costs for the local health economy and should improve patient access; however, under PbR this would reduce the income of hospital ophthalmology departments. We were given a PowerPoint presentation (Microsoft Corporation, Redmond, WA, USA) presented by llett and Kimber[184] on the results reported by Community Ophthalmology Team (COT) on demand management with relation to the local trust (in the context of large numbers of false-positive referrals). COT reported high patient satisfaction rates; a 9.5% referral rate to secondary care; a 'did not attend' rate of 4.5% (as compared with 10% at the trust); and forecast year-end savings of £33,000 minimum (as compared with direct referral to the trust).

This raises the issue of how PbR impacts on technology adoption, including its effect on UFRI. This is discussed next.

## How does Payment by Results impact on the adoption of ultrawide field retinal imaging?

Under PbR, trusts are funded on the basis of activity. In secondary care, non-urgent ophthalmology referrals from primary care are a significant source of income to trusts.

> *The trusts are making money, so there is a disincentive [to transfer patients to primary care]. They're actually happy with the false positives because they get money for old rope.*
>
> *Optometrist, HSO*

Even if referrals turn out not to have been appropriate ('false positives'), under PbR there is no incentive for the trusts to work with commissioners on 'demand management'.

> *From a PCT point of view, clearly we're looking at the appropriateness of referrals to the trust. Everybody's [all PCTs] trying to do demand management … We've picked five areas to look at, one of which is ophthalmology … orthopaedics, ENT and ophthalmology are our biggest referring specialities … In ophthalmology we have 16,000 new appointments each year … we [in the PCT] know that there are lots of referrals made that could be managed in primary care, or by opticians.*
>
> *Lead commissioner for WIS, PCT*

Yet, as discussed above, a proposal to open an eye clinic in primary care staffed by optometrists was 'stamped upon' by one of the secondary care ophthalmologists. The reaction of one powerful hospital ophthalmologist may be seen, in part, as professional hostility towards optometrists expanding their skills but it may also have been triggered by the possibility of eventual loss of income to ophthalmology departments in secondary care. Although, at first, the introduction of Eyemaps into primary care would be likely to increase referrals as more disease was detected:

> *So the consequence of having Eyemaps in every optician would be more referrals. So it'll be good for business for the hospital.*
>
> *Consultant ophthalmologist, TC1*

Over time, as optometrists improved their abilities to interpret the Eyemap images, referrals should become more appropriate, in terms of both false positives and false negatives. This process could be greatly facilitated by education. As mentioned earlier, the Eyemap producer has hired a specialist in the USA to whom images can be sent for comment.

> *If you have a support mechanism … Eyemap use a very good guy in America, and rather than refer the patient to hospital I refer to him first … Tell me what it is, what you think it is. And you get a response back.*
>
> *Optometrist, HSO*

However, clearly this is a somewhat ad hoc solution that, although helpful at the level of only one specialist, could not support all optometrists if the adoption of Eyemap became widespread in primary care.

### *Education across the tertiary–secondary and primary care interface?*

Education across the primary–secondary care divide would be a necessary aspect to the effective use of Eyemap in primary care, but currently ophthalmologists are unlikely to agree to participate. Under PbR, there is no tariff for education. Hospital managers are unlikely to allocate time to ophthalmologists to educate optometrists when this process, over time, would be likely to reduce referrals, and therefore income, to the hospitals.

> *Then the question is how do you allocate the time for doctors to look at all those results? You can't just receive them [Eyemap images] in your pigeonhole and expect to be able to provide all those*

> *diagnoses as part of your admin session. If you're going to provide that sort of opinion, you need to have allocated time to sit down and look at those images properly. And I don't think the NHS is going to do that now [under PbR].*
>
> *Consultant ophthalmologist, TC4*

Indeed, where the hospital concerned devolves resources to specialities, and the specialty concerned accumulates a surplus, clinicians also will be reluctant to engage with educating primary care if this might reduce their income.

> *At [WIS] the clinicians run their own businesses, we have a very distributed and devolved business culture within the trust … they retain 80 per cent of the money, core centre only keeps 20 per cent … Our ophthalmology unit has an accumulated surplus and to spend all they have to do is write a note to the board, explaining that they want to buy X Y Z and within the set parameters and policies, the presumption is the Board will approve it.*
>
> *Business Development Manager, WIS*

There are policy expectations that commissioning should drive technology adoption but commissioners are not in a position to assess the clinical utility of a technology. Therefore, they see the decision to adopt as an *internal* matter for the trusts.

> *The trust may want to look internally at business cases for technology, but we don't buy consultants, we don't buy equipment anymore, we buy outcomes. We're not against technology if it improves efficiencies. From a commissioning point of view it's about the patient outcome.*
>
> *Lead commissioner for WIS, PCT*

As is clear, PbR funding, along with devolution of resources to specialties, offers incentives to clinicians to work harder to increase the throughput of patients, but this is limited to specialties or at best to the whole hospital. At present PbR is a disincentive to work across the secondary–primary divide and to cede what are profitable activities for secondary care to primary care. The UFRI technology is an example of a technology that could be used to advantage in primary care, but the longer-term consequence of reduced referrals is unlikely to be welcomed in secondary care.

### *Funding sources for ultrawide field retinal imaging?*

However, even *within* hospitals, PbR impedes the adoption of UFRI as there is no tariff for the technology. Indeed, until recently there was no tariff for photography at all.

> *Up until recently, there's been no tariff for photography. We don't get a fee if we take a photograph. I mean, there are tariffs for a new patient, tariffs for a follow-up and tariffs for certain procedures, but photography has not been on tariff. So the costs will be covered by the new patient fee or the follow-up fee. So then if you want to get a camera, you've got to put a business case in to say we're going to spend £50,000 or whatever it is.*
>
> *Consultant ophthalmologist, TC1*

The lack of a tariff for UFRI was a barrier in the present study. Without a tariff (or other sources of funds), clinicians had to write and present a business case to trust management. Income generation was thought to be the ultimate basis for such a case.

> *You won't get it [the business case approved] if you just say 'The big colour pictures, they're good quality and it's more interesting,' nobody's interested in that. You've got to generate more money … quality of care is important, absolutely, but the bottom line will be can you generate money as a consequence of it?*
>
> *Consultant ophthalmologist, TC1*

Clinicians are busy people who are not skilled in writing business cases. Although the tertiary specialist quoted above had finally had his business case approved, previously there was reliance on charitable money.

> *In our department, almost everything, all our photographic equipment, in fact an awful lot of infrastructure, has been paid for by charitable money … It's very hard to buy equipment through the hospital, it's partly because there is no tariff, so it's hard to write the business case to do it. Partly we had charitable money, so the trust says, oh well, you've got the charitable money, you'd better spend that rather than spending their [the trust's] money.*
>
> *Consultant ophthalmologist, TC1*

Without secure funding, other tertiary specialists relied on ad hoc revenue sources, including patients:

> *Now the [Eyemap] costs well over £100,000, to lease costs £2,200 a month. The hospital refuses to pay for it, so I'm paying for it from our patient donations … on their last visit when we tell them [patients] goodbye they get a letter saying they were helped by previous donations and so hopefully some of them will give us some money and we will be able to afford the Eyemap a bit longer.*
>
> *Consultant ophthalmologist/ocular oncologist, TC3*

Somewhat paradoxically, only at WIS, where the ophthalmologists declined to proceed with UFRI, had money been raised from a PCT; presumably the PCT agreed to fund the technology in the hope of cost savings for the health economy as a whole:

> *I secured a hundred thousand pounds from our primary care trust to actually fund the technology*
>
> *Business development manager, WIS*

This chapter now summarises the barriers to the adoption of UFRI, briefly compares the issues over this technology with those relating to IPT and BLNA and notes the failure of the ANT principles in this case.

## Discussion and summary

As highlighted at the beginning of this chapter, *where, how* and *for what* issues are not yet fully decided with respect to UFRI. Domestication is a term used in the social studies of technology, a metaphor implying that a technology has to be 'tamed' before it can find a place and fit into practices and routines (see, for example, Berker *et al.*[185]). UFRI is a technology that is not yet domesticated. A place had been secured in tertiary care but, unlike IPT and BLNA, where the place for adoption was uncontested, it was unclear and subject to professional dispute if UFRI could be successfully used in secondary and primary care. Moreover, unlike IPT and BLNA, there were differing professional opinions over, first, the extent to which UFRI was proven; second, the clinical utility of UFRI; and, third, the target conditions for which the technology is best deployed. There was some consensus over these three in tertiary care, but this knowledge was not being diffused out to secondary and primary care.

We have argued in a previous chapter that the NTAC processes are based on ANT principles. In ANT terms, the agency of any human or non-human actant always depends on the power of the network within which it is embedded.[88,159] The possibility of embedding UFRI in a network, and thus ensuring its agency, is problematic. One attraction of ANT, for this research, is that networks transcend organisational boundaries as they extend themselves spatially.[186] One of the key characteristics of UFRI is that it could benefit patients and the health-care economy as a whole through enabling cost-effective earlier diagnosis of serious eye conditions, which could result in loss of vision. However, as evidenced here, the potential for embedding UFRI in an educative network that brought primary, secondary and tertiary care clinicians together to enable earlier diagnosis seems, currently, remote. The division between primary and secondary–tertiary care, the financial incentives for activity in secondary care and professional jurisdictions currently all

conspire in the UK to keep UFRI confined to specialist use in tertiary care, along with a few entrepreneurial optometrists. Even sharing knowledge across specialists in tertiary care faces obstacles. One specialist required us to sign a confidentiality agreement before he agreed to be interviewed, on the grounds that his research using UFRI gave him a competitive advantage over his peers. Yet the potential for UFRI to improve patient care remains. Aside from detection and diagnosis, the tertiary specialists remarked on the possibilities for Eyemap to advance their knowledge of ophthalmological conditions.

The UFRI technology did not go forward as a project, but, even if it had, from the evidence in this chapter it seems unlikely that it would have succeeded, as the barriers to implementation of this technology were so complex and difficult to overcome. Only measures to achieve some integration between primary, secondary and tertiary care, so that knowledge can be transferred upstream from tertiary, through secondary and onwards to primary care, would improve the adoption of this technology. In *Chapter 8* we reflect on whether or not current government policy (as exemplified in *Innovation, Health and Wealth: Accelerating Adoption and Diffusion in the NHS*[1]) can improve adoption and implementation rates for 'hard to domesticate' technologies.

# Chapter 6 The insulin pump therapy case study

## Introduction

This case study focuses on IPT, used in the treatment of type 1 diabetes. Type 1 diabetes is a long-term condition that affects around 250,000 people in the UK and requires lifelong treatment with insulin.[187] Rates of type 1 diabetes have been increasing over time, with the greatest increase in children younger than 5 years of age. People with type 1 diabetes are unable to produce the natural hormone insulin, which is needed to control and use glucose. Most people with the condition control their diabetes through multiple daily injections (MDIs) of insulin. IPT, also known as continuous subcutaneous insulin infusion (CSII), is an alternative method of treatment to insulin injections by syringes or insulin pens. The pump provides a CSII, thus replacing the need for MDIs and typically producing better control of blood glucose levels.

Insulin pump therapy was first introduced in the UK in the 1970s, initially within the context of research studies on type 1 diabetes. However, mainstream adoption of the technology was limited, linked to concerns about efficacy and safety and the potential financial burden on the NHS.[188,189] In the past decade, technological advances have resulted in a new generation of smaller, more portable, more efficient and user-friendly pumps with additional safety features.[189–191] Several studies in recent years have demonstrated the benefits of IPT in type 1 diabetes compared with MDIs.[190,192–199] In particular, it is suggested that the continuous infusion of insulin provides not only improvement in metabolic control, but also increased physiological and psychological well-being.[189,200] Other benefits include improved patient outcomes [e.g. lower glycated haemoglobin ($HbA_{1c}$); $HbA_{1c}$ is a measure of the average plasma glucose concentration over a period of time, in people with diabetes, a higher plasma glucose concentration indicates poorer control of blood glucose levels], reduction in all grades of hypoglycaemia (hypoglycaemia is a low blood glucose level, which is too low to provide sufficient energy for the normal body functions), a reduction in blood glucose concentrations, fewer blood glucose swings, and a lower daily insulin dosage compared with insulin injection therapy.[201] It is also suggested that quality of life for patients and their family and treatment satisfaction are likely to be better on pump treatment than on MDIs,[145] particularly for people who have experienced significant and continued control problems on MDIs.[201] However, comprehensive patient education, such as carbohydrate counting, and frequent self-monitoring of blood glucose or continuous glucose monitoring are necessary components of successful IPT.[190]

The IPT case is the only one of the three technologies studied that had been the subject of a national technology appraisal process; however, this did not guarantee that the evidence base for the technology was universally accepted, as the findings illustrate. NICE issued technology appraisal guidance on IPT in 2003, which was further updated in 2008, and recommended it as a clinically effective and cost-effective treatment option for people with type 1 diabetes, whether adult or child, for whom MDIs have failed, and for children aged <12 years if MDIs are not deemed practical or appropriate.[202] Alongside the technology appraisal, NICE produced a commissioning guide to help health service commissioners plan and deliver services in line with the guidance. This suggests that the standard benchmark rate for the uptake of IPT should be 12% of people with type 1 diabetes, and 33% for children younger than 12 years old.

A national working group on insulin pump services[203] used a variety of sources, including national registers, manufacturers' records and published reports of pump practice in various countries, to estimate the uptake of IPT at an international level. These data suggested that some countries (USA, Israel and Germany) were using pumps for about 15–20% of people with type 1 diabetes. A typical figure for Europe (e.g. France, Sweden and the Netherlands) was around 10% of people with type 1 diabetes using insulin pumps for routine management. In contrast, overall UK pump usage was estimated at around 1% of people with type 1 diabetes using insulin pumps for routine management.

A subsequent review of IPT in England was undertaken by the Medical Technology Group in 2010.[204] They carried out a survey of all PCTs ($n$=152) in England to ascertain levels of insulin pump provision. Of these, 87.5% responded to the survey and the data indicated that the average rate of pump use was 3.7%, with rates across the country ranging from 0.25% to 13%.[204] Thus, although the rates were higher than those estimated by the Department of Health Working Group in 2007, they were still some way from the NICE recommended benchmark of 12% and considerably lower than in most other countries of comparable economic standing and level of health-care provision.

## The NHS Technology Adoption Centre project on insulin pump therapy

NHS Technology Adoption Centre selected IPT to go forward as a technology implementation project so that it could identify the challenges associated with implementing IPT and suggest ways to overcome them. Three NHS trusts were selected to work as implementation sites; these were organisations that responded to the NTAC call for implementation sites and were selected because they wanted to develop their IPT service in line with NICE guidance (see *Chapter 4* for a more detailed description of the NTAC selection process). Three MSs were identified to work with the implementation sites, these were organisations that were already using insulin pumps with many of their patients and could provide clinical mentorship to the teams in the implementation sites. The experiences of the sites involved in the IPT project were collated into a HTWT guide.[205] This was intended as an online resource that could be used to help the adoption of IPT throughout the NHS.

## The case study

The main data collection took place in four NHS organisations: two NTAC implementation sites for IPT; one MS; and one organisation that had initially applied to be an implementation site, but was not selected by NTAC. This latter organisation was keen to increase the use of pump therapy and, as such, would be typical of the organisations that NTAC was aiming to target with the HTWT guide. In all sites, interviews were conducted with a range of individuals involved in implementing IPT, including commissioners, clinicians, diabetes nurse specialists and business/procurement managers. A total of 23 interviews were conducted across the four sites; details of the interview sample by site are provided in *Table 3*.

Alongside these qualitative interview data from the case study sites, supplementary sources of data included a survey of clinicians about IPT use in the NHS in England and documentary analysis of e-mail correspondence received by the patient support group INPUT between September and November 2011.

Before presenting the main findings relating to the IPT case, some brief background information on each of the four NHS organisations studies is outlined, along with a summary of the results of the survey we conducted on IPT uptake in England.

### *Implementation site 1*

The first site that worked on IPT with NTAC was an NHS trust providing acute services that had been formed from the merger of two trusts some 8 years earlier. Diabetic services were provided at two separate sites and the acute trust had two main commissioners. The trust was in the process of applying for foundation trust status. One of the two main acute hospital sites had a history of interest in using IPT and was very receptive to the adoption of the technology; the second site was less enthusiastic about the technology. However, prior to their involvement with NTAC, there were no formalised processes or systems for managing the introduction of IPT at an individual patient or service level.

**TABLE 3** Interviewees for the IPT case study

| Organisation | Number of interviews | Interviewee role/job title |
|---|---|---|
| IS1 | 7 | Diabetic consultant |
| | | Diabetic specialist nurse ×2 |
| | | Project manager (dietitian) |
| | | Commissioner |
| | | Procurement manager |
| | | Finance manager |
| IS2 | 5 | Diabetic consultant |
| | | Diabetic nurse specialist ×2 |
| | | Contracts manager |
| | | Finance manager |
| MS | 4 | Diabetic consultant |
| | | Diabetic nurse specialist |
| | | Commissioning manager |
| | | General (service) manager |
| NIS | 7 | Diabetic consultants ×4 |
| | | Diabetic nurse specialist |
| | | Specialist medical trainee |
| | | Clinical manager |
| Total | 23 | |

IS1, implementation site 1; IS2, implementation site 2; NIS, non-implementation site.

### *Implementation site 2*

The second implementation site was an NHS foundation trust providing specialist children's services, commissioned from a wide range of primary care organisations (around 17 in total). The pressure to provide IPT had particularly been driven from the patient population (children and parents); as a consequence, the diabetic team was keen to become more skilled and up to date in terms of providing pump services.

### *Mentor site*

The MS was an NHS foundation trust, providing an integrated hospital, community and primary care diabetic service. The trust had originally applied to be part of the NTAC implementation project, but had been seen to be relatively well advanced in terms of the adoption of IPT and, therefore, did not meet the early adopter criteria. As a consequence, it was invited to act as a MS for IPT (although in reality they received limited requests for advice or information from the implementation sites). The trust had an internal manager with responsibility for commissioning, who acted as an interface with the PCT to develop and negotiate contracts, an arrangement that had worked particularly well in the introduction of IPT.

### *Non-implementation site*

The fourth site was a specialist diabetes centre, hosted by an NHS foundation trust. The centre had only recently moved from a primary to secondary care setting, as a result of the changes to commissioning in

the NHS. On account of its specialist status, the trust dealt with a large number of commissioners, across a wide geographical area. The introduction of IPT had been led by a clinical academic, who had submitted an application to become an NTAC implementation site for IPT. This application was unsuccessful; however, the consultant and some of his colleagues had continued to try to develop their pump service without NTAC's input.

## Uptake of insulin pump therapy: survey findings

As outlined in *Chapter 3, Research methods* and *Data analysis* and *Appendix 3*, we conducted an online survey of a network of UK clinicians actively engaged in trying to increase IPT uptake to assess the current level of uptake of IPT. *Table 4* summarises the key findings from this survey, comparing estimated uptake of IPT in May 2012 with uptake levels 3 years previously.

These data suggest an increased use of IPT, in line with the findings of the Medical Technology Group survey of 2010. However, they also indicate that, in summer 2012, 65% of respondents reported that pump use was lower than 10% in their NHS trust (in other words, below the 12% target recommended in the NICE guidance). Moreover, of the 62 respondents working in trusts where the uptake rate of IPT was < 5% 3 years previously, only 29 (47%) had managed to raise this level to >5%.

Our qualitative data collection attempted to explore in more depth the reasons for the lower than recommended uptake of IPT in the NHS in England, and the difficulties encountered in attempting to increase the uptake rate. Analysis of the findings reveals a number of key themes in terms of factors that appear to facilitate or hinder the adoption of IPT, ranging from those on the individual level, including patient- and clinician-focused factors, through to more organisational- and system-level issues relating to past history and experience of IPT including resourcing, financing and commissioning issues. Each of the key themes is discussed in more detail in the following sections.

## The patient pull for insulin pump therapy

A number of patient level factors appear to be important in terms of the adoption (or otherwise) of IPT. These include patient-driven demand for the service, acceptability of the technology and the importance of patient self-management of the technology. In relation to the first issue, views differed in terms of the extent to which patient demand was important in driving the introduction of the technology. In some cases, patient requests for IPT were seen to be a major driver:

> *We are very good at being ahead of our patients in what they know about either their condition or their treatment plan or their medications. But with insulin pumps, there was a feeling that we were*

**TABLE 4** Percentage of patients with diabetes estimated by respondents to be using IPT

| Estimated percentage use | May 2012 (%) | 3 years previously (%) |
|---|---|---|
| <5% | 38 | 70 |
| 5–10% | 27 | 16 |
| 10–15% | 14 | 10 |
| >15% | 22 | 2 |
| Unknown | 1 | 2 |
| All patients | 100 | 100 |

> *only just one step ahead of our patients because they came in so suddenly really that the patients were asking for them and we were saying, 'Oh, hang on a minute. We're not so sure that we have the skills and knowledge to facilitate this for you.' So there was a definite perceived, you know, we weren't skilled enough to run these kind of programmes.*
>
> *Diabetic specialist nurse, IS2*

By contrast, other interviewees did not perceive a significant patient demand for pumps; rather they felt that it tended to be the clinicians who raised the possibility of using a pump as an alternative to MDIs.

> *One of the things that I have noticed when I've been to meetings and so on elsewhere that some of the people say patients ask for pump therapy. It doesn't happen in my experience very much … Yes it tends to be us that says, well actually I think you might benefit, would you consider a pump? There is also a significant turning down of going on pump therapy.*
>
> *Diabetic consultant, IS1*

Linked to the above point, there was a fairly consistent view among many of the clinical staff interviewed that there were issues relating to patient acceptability of pumps that accounted for some of the lack of uptake of IPT. For some patients, this was about how the pump would fit in with their lifestyle or how they felt about having to be attached to a pump at all times; for others it was the requirements that went hand in hand with using a pump, for example the need for active self-management and regular blood glucose monitoring.

> *There are a significant number who think about it and then just don't want even to take anything any further. They're clear in their own minds that they don't want a pump. And I think the minority are the ones who would be prepared to consider a pump and they then go on to have an assessment, a formal assessment. And of those who go forward, not everyone in the end decides that they want a pump. Having seen one, talked about it in more detail, quite a number of them have come to the conclusion that it's not for them …*
>
> *Diabetic consultant 3, NIS*

However, for others the pump was seen to provide them with a greater freedom to manage their diabetes, despite some initial concerns about the pump itself:

> *Well there's the body image, which probably is more of a concern for females, understandably … There's a classic quote where the partner calls them the Bionic Man or Bionic Woman because they are linked up to the machine. Certainly in my study … I think the patient experience is honestly amazingly positive. Even people who have apprehensions about going on the pump, but still probably want to do it because their control is not where they want to be or they've got severe hypos, generally speaking a few months into pump they would not go back to injections.*
>
> *Specialist medical trainee, NIS*

The comments above represent a rather divergent set of opinions on patients' views of IPT from the perspective of professionals delivering the service. It also appears that professionals' views do not always correspond with the views of patients themselves. This is illustrated by some of the e-mail correspondence received by the patient support group, INPUT.

> *[My] consultant said: 'If you use a pump you will be a failure to yourself.' 'It's not suitable for you because you work.' 'If you have to miss a meal you'll be in trouble because the insulin is going in all the time.'*
>
> *Patient A with type 1 diabetes*

*My daughter has had diabetes for 4 years. The clinic team are saying it's not the right time for a pump. She is aged 9, will be 10 in April. [Her] control is very poor. The diabetes clinic said 'how would we work out her pump ratios when she's so up and down?'*

*Parent of child B with diabetes*

### *Achieving effective self-management of pumps*

Despite some differences of opinion on the level of acceptability of pumps to patients, there was more consensus on the need for effective self-management by patients using pumps, including educational preparation and support to use the pump. This included regular monitoring of blood glucose and a level of understanding to interpret the results and adjust the pump settings accordingly.

*When a patient goes on a pump, initially, it is … very time-consuming, the patient needs lots of education … the thing about the pump it, whether it works or not, depends on patients' self management. Now, for a patient to be able to self manage the pump, they need to be, learn a lot about the pump. They need to learn all the pump functions, they need to know what to do if they hypo, if their blood sugars are high …*

*Diabetic specialist nurse, IS1*

In the case of children, the second implementation site had identified a number of additional criteria to determine which children were eligible to be started on pump therapy.

*As long as they've got at least one English speaking parent because, as you can imagine, it's quite tricky to train somebody who doesn't read and speak English to use that level of technology. If you've got one parent that speaks and reads English, we can go for it. And we've had ten children in the last two years go straight onto insulin pumps from diagnosis. So there is no [lower age limit] – and they actually work really, really well for tiny babies.*

*Diabetic specialist nurse, IS2*

## The influence of clinicians on the implementation of insulin pump therapy

Clinician-related factors appeared particularly influential in the adoption of IPT; this was particularly the case at a consultant level. Where consultants providing a diabetic service were motivated and enthusiastic about IPT, they played an important role in leading the introduction of the technology.

*… we have always been a forward looking trust I think, although we are only a district general hospital I do think that we have a philosophy of, the philosophy that we have in this department is that our patients should not miss out on any treatment that could be of benefit to them and that is available in the UK and that's how it has always been.*

*Diabetic consultant, IS1*

*Equally, where consultants were sceptical or wary of the technology, they represented a significant barrier to its implementation. For some clinicians, this appeared to relate to bad experiences of using pump in the earlier stages of developing the technology, alongside some more recent negative incidents.*

*And you have to remember that I did actually use pumps in 1982, so I've been using pumps for a very long time … So I'm not sceptical because I've had nothing to do with them. I'm sceptical because I've seen the good things and I've also seen the bad things about pumps. Like the girl we admitted last weekend, in very severe diabetic ketoacidosis [ketoacidosis is a dangerous complication of diabetes caused by a lack of insulin in the body], with a pH of 6.8, who nearly died, and I'm not egging this up because she'd … we hadn't put her on a pump, she was put on a pump elsewhere and she didn't self-manage properly. When she felt sick, she took her pump off and she was that close to dying.*

*Diabetic consultant 3, NIS*

In other cases, resistance appeared to be tied up with local politics and personalities:

> *And that's one of the sort of barriers … internal barriers to implementation and it just kind of reflects the bigger picture I think and problems within the sort of structure of the team that was highlighted by this project. So I think some of the barriers to this project aren't really barriers to this project, they're more to do with identifying barriers that are within … our Diabetes Team … one individual in particular who was asked to be involved but because of other work commitments he wasn't, couldn't get involved but if it isn't his project he doesn't want to know and he has done quite a few things to try and sabotage the … and he's still trying to do things to sabotage it. It's not just in this, it's in other things as well. And those are the sort of kind of things that actually aren't necessarily surmountable.*
>
> *Project manager, IS1*

## The strength of evidence for insulin pump therapy

One particular issue that emerged, and may partly account for the differences of opinion at a clinical level, was the strength of the evidence supporting the introduction of IPT. Some clinicians perceived the evidence supporting the use of IPT as rather 'shaky'.

> *I don't think we have the evidence yet and that is a really important question. I think it was an assumption when we started our journey with pumps really so hopefully if you can get people good at this then their needs for support get less. I don't know if that's born true and I think this comes back to your patient selection that you need to be very careful about the reasons that the patient is selecting a pump. The one thing that it does not do is take away your diabetes it makes it even more in the front and you know whether they are able to manage it themselves and again I think we haven't to my knowledge got very good data on long-term outcomes from our pump clinic.*
>
> *Diabetic consultant 4, NIS*

> *I'm not even a hundred per cent sure about the proven clinical benefits. If you have … do the proper randomised controlled trial, pump versus intensive therapy with an equivalent amount of input from health care professionals, you don't get a great difference in $Hb_{1c}$ or in anything else. You might get a difference in patient satisfaction in favour of pump, but that's in folk who want to go onto the pump. So I think sometimes the benefits of pumps are a bit overstated.*
>
> *Diabetic consultant 3, NIS*

This second quote raised an issue that a number of interviewees at site NIS referred to: whether it was the additional educational input and support that pump patients received that made the most difference, as opposed to the technology itself. However, at other sites, the evidence for pumps was much less disputed, with IPT being described as a 'proven technology'. With the endorsement from the NICE technology appraisal that IPT was a clinically effective and cost-effective treatment, this has enabled organisations to develop a case for their commissioners for increased funding of IPT.

> *I suppose, on the surface, it looks expensive but there's then the evidence to show that … that's why NTAC have taken it on … because the improvement of the blood result, $HbA_{1c}$, in preventing complications … is a proven technology for improving progress with [diabetic] complications.*
>
> *Diabetic specialist nurse 2, IS1*

> *PCTs have to follow NICE, have to be seen to be following NICE guidance, so I know it's a time of austerity and the PCTs have other priorities, but a trust should always play the NICE guidance card and say, look you know, that's why we've got NICE guidance because it's the best outcomes for this group of patients.*
>
> *Diabetic specialist nurse, MS*

However, there were some who were critical of the wording of the NICE guidance, which indicates that IPT should be used where MDIs have not been effective in controlling blood glucose levels. This led some interviewees to suggest that IPT was perceived as a 'treatment of failure':

> *And at the moment, very much NICE guidance is geared to pump use being used as a treatment of failure. So if you fail with your multiple daily injections, i.e. you've still got poor control, or you've still got low blood glucose. It's a negative process … it's sort of like a downward staircase on diabetes. Start on maybe twice daily injections or your control is not very good – let's put you onto the next treatment, which might be structured education and basal bolus regime [a basal-bolus regimen, which includes an injection at each meal, attempts to roughly emulate how a non-diabetic person's body delivers insulin]. Oh you've not done well with that, you've failed with that. Right, let's go onto something else. And eventually you get to pump therapy. By that time, the question is, is the patient demoralised, is the clinician demoralised? Why is pump therapy used as the treatment of failure, if it's supposedly the best treatment? Compared to cancer treatment, you wouldn't … We'll start with something but if you don't get better then we'll use the next one. Whereas in diabetes, it is like that.*
>
> *Specialist medical trainee, NIS*

This could lead to a dilemma as to how to proceed with patients who might benefit from a pump, but did not meet the NICE criteria.

> *But there are definitely people whose diabetes control is okay but actually they probably would do better if they were on a pump, but that's not covered by NICE guidance, so they're currently excluded and you can't really encourage them to let their $HbA_{1c}$s go up, which you know some of the conversations that not just us have had but we've you know … well do you let them increase their [blood glucose] … so they meet the criteria?*
>
> *Project manager, IS1*

## The initial investment costs of insulin pump therapy

A key issue relating to the introduction of IPT was the service investment required, including the availability of specialist pump trained nurses, educational preparation of patients to use a pump, and the cost of purchasing pumps and related consumables. The upfront investment costs in terms of staff and patient education were seen to be significant. Furthermore, several interviewees raised questions about the extent to which investing in service development for the introduction of IPT took services away from non-pump users and could result in inequity.

> *And I think the other barrier is the fact that, certainly in [this organisation], we expend a great deal of health care time with the small number of people who are on pumps and that is to the detriment of people who are not on pumps. We have a limited number of physicians, nurses, dieticians and if they're working with pumps, it means that they're not working with our other non-pump population. And I think we have a tension there; that the more resources we devote to pumps, the less we've got for somebody else. So it's not just the cost of the pump and the pump consumables, it's the health care professional time as well.*
>
> *Diabetic consultant 3, NIS*

Others raised concerns about the costs of the technology itself, suggesting that the cost was kept unnecessarily high by the producers, which, in turn, acted to limit the wider scale uptake of IPT.

> *So there's been a lot of input from the pump manufacturers, but then there ought to be because prices of the pumps is ridiculous. And if you want to ask about the constraints, I've said it to everybody so I may as well say it to you, if an iPad can be 600 quid, why is an insulin pump £3,500? … And if – it strikes me that it's not any technical – I don't know anything about technology, but I think they're milking it. And if you could even – that's your – that's your biggest constraint.*
>
> *Diabetic consultant 2, NIS*

## Funding and commissioning insulin pump therapy

Each of the four sites had different arrangements in terms of the commissioning of IPT services. In the first implementation site (IS1), the trust had a close working relationship with commissioners. The PCT had been instrumental in driving the adoption of IPT and agreed to provide funding for the service without a formal business case.

> *So that's when I got involved, I suppose that's why they're saying it's been driven primarily by the PCT because once I became involved, I did actually start trying to structure it and say, you know, let's look at it in a more comprehensive way; rather than just clinicians thinking this is a great thing to do, without any thought about how we're going to pay for it.*
>
> *Commissioner, IS1*

> *… unlike other places we don't actually have anything signed between the PCTs and us, we didn't have to do a business case or anything. We sat around the table….*
>
> *Diabetic consultant, IS1*

The second implementation site worked with a large number of commissioners, which could cause difficulties as different commissioning bodies had different ways of working.

> *I think what's difficult is they all have a different way of working. For example, the main PCT that we work with … are quite happy to be invoiced directly by the insulin pump companies. I order a pump and the consumables from the pump company; they invoice the PCT; the PCT pay the bill. The patient then starts ordering consumables from the company and the PCT get the bill. That's brilliant. I don't have to have a cupboard full of stock. I don't have to sign off invoices. I don't have to get involved. So that works really well. Then you have another PCT, who shall remain nameless – there are two or three of them – where they insist on recharging back to the children's hospital, who then have to pay the company, and then the company will supply. And then the bill will come back to the children's hospital, we pay the bill, then we recharge the PCT … So you add another step. An unnecessary step in some respects, but it's in there … And the other problem that that then causes is the PCTs do not get any bulk buying discount and they are missing a trick …*
>
> *Diabetic specialist nurse 1, IS2*

In the MS, the acute trust had a commissioning manager who acted as a point of liaison and negotiation with the PCTs, which was seen to have played an important supporting role in the introduction of IPT.

> *… not every trust has got like my post and my team that can be the conduit so sometimes the individual departments struggle with, who do they speak to within the PCT or we can help with that. We facilitate it, we package it in a way we know the PCTs would be amenable and so I think that's quite important … We call it commissioning, which is a bit of a daft name, … so we agree the contracts, we agree the quality in the case of the PCT, we're always mindful of whatever we agree is, I've got an inward looking role and an outward looking role and we've got to keep that, that communication going both ways from my department basically.*
>
> *Commissioning manager, MS*

In the fourth (non-implementation site; NIS), the organisation had been used to working on a block contract arrangement and had discretion over the use of their resources, which meant they could decide the level of investment they made in pumps. This was initiated when a clinical academic consultant came to work in the service and was interested in establishing a pump service. However, the consequence was that the service had largely grown around the practice of this particular clinician without being more widely adopted by or embedded in the rest of the organisation.

> *[The consultant] … was told in no uncertain terms that he could not develop a service bigger than that because he was an academic … It was not clear what his long-term shelf life would be … so he could then leave me with a huge number of people on pumps … We have to be quite careful that if he did move we're then not left with a service and nobody and no budget to cover it.*
>
> *Clinical manager, NIS*

In summary, the implementation and MSs were able to get the PCTs to fund IPT because of the NICE guidance and, as a consequence, they were not particularly worried about the lack of a national tariff for IPT. Indeed, having the PCT pay directly for the costs was seen to be an advantage, as a tariff only provides the average national cost, which may be less than the actual cost.

> *I guess the danger with having a specific HRG [for the pump service] is making sure it reflects the cost and responds to changes in cost. Whereas the advantage to us at the moment is we don't have to worry about it. If someone's having a pump, the PCT pays for it direct.*
>
> *Diabetic consultant, IS2*

However, a persistent concern raised related to the infrastructure required to establish an IPT service, in terms of nurse specialist provision and patient education (as discussed in the previous section); this was a cost that the organisation typically had to absorb as part of setting up the IPT service.

## The role of NHS Technology Adoption Centre in supporting implementation

NHS Technology Adoption Centre clearly played a key role in supporting the implementation of IPT for the two implementation sites. This included acting as an initial catalyst to 'do something' about IPT, introducing a formal project management structure, providing a map of how to get started and implement IPT and developing the systems that were needed to support the use of the technology (see *Chapter 4* for a description of the NTAC process of working with implementation sites).

> *I mean I think it was if you like the catalyst, participating in this project was the catalyst that we needed to get us to focus on this.*
>
> *Diabetic consultant, IS1*

> *They [NTAC] were phenomenally helpful. We knew where we wanted to be, but weren't sure of the map to use to get us there … NTAC were really good in helping us to get the people in the room who needed to be in the room, to have the right conversations. Project management – I think that's what we really lack and what they did really well.*
>
> *Diabetic specialist nurse, IS2*

> *That's the difference with NTAC. It's a project. One of the things that's come out of it, I would say, is that there's been joint working with commissioners and PCTs and a recognised procurement process … The whole problem in the past is that you had patients waiting for pumps but it was either applying for funding individually, … or finding an ad hoc way of doing it.*
>
> *Diabetic specialist nurse, IS1*

The NTAC method of supporting technology adoption seemed particularly suited to the sites attempting to introduce IPT, providing a co-ordinating structure and project management that had been lacking, despite prior enthusiasm or intent to support IPT. The lack of a co-ordinated approach to IPT provision is equally apparent in some of the patient feedback received by the support group INPUT:

> *My consultant supports my belief that an insulin pump should now be tried as soon as possible and referred me to a Dr X at the X Diabetes Centre. Dr X has agreed that a pump should be tried soon, however he has warned me that there may be a delay of possibly 5 months before the local PCT gets around to agreeing to this proposal.*
>
> *Patient C with type 1 diabetes*

> *I would like some guidance if possible on how much choice I have on the insulin pump that is provided for my 5 year old. We have had funding approved for a pump, although the pump of our choice – we are told is too expensive by the PCT. Our hospital have said they will support us in whatever pump we choose if we can obtain funding, but have also said that if we don't make up our minds soon the funding will be retracted.*
>
> *Parent of child D with type 1 diabetes*

Although acknowledging the important input that NTAC provided in structuring and signposting the implementation of IPT, there was also a view from some interviewees that the hard work only started once the NTAC project was coming to an end and they had to actually implement all the things they had planned on paper. In one of the two implementation sites, this responsibility sat with an internal project manager for IPT.

> *Well, it's like anything; the pump project is in some way a theory. It was setting a structure, having guidelines, having a structure to every stage of pump therapy, but then, whatever we've decided now as part of this pump project – you've got to put it into practice! … That's when the real hard work starts, doesn't it? Up to now it's been on paper.*
>
> *Diabetic specialist nurse 2, IS1*

### *How to Why to guides*

Overall, the case study sites had limited involvement with the HTWT guides. Although the two implementation sites had been involved in the development of the guides, the first site had received almost no contact from other organisations asking for information or advice since the publication of the guide. This was the same situation in the MS studied and there was a view among the interviewees that the guide could not substitute for the hands-on project management support provided through working with NTAC.

> *I'd like to be able to show you some examples of where the How to Why to guide has been used and someone's done what we have done, but my worry is that it's quite hard without that push from NTAC centrally.*
>
> *Diabetic specialist nurse, IS2*

The exception to this was IS2, where one of the diabetic nurse specialists reported using the HTWT guide to direct people who contacted the trust for advice and guidance on setting up a pump service.

> *I've [directed] an awful lot of people to the How To Why To guide … I used to get a lot of calls saying, you know, 'How do I get my pump service up and running? How do I get more kids on pumps? What do I do?' and you'd spend, you know, forty minutes on the phone. The How To Why To guide has saved us loads of time because you can say, 'Go on and track it through,' and all those questions you're likely to ask are answered. And there are templates on there for doing a business case.'*
>
> *Diabetic specialist nurse 2, IS2*

## Discussion and summary

Overall, the NTAC process seemed relatively well matched to the needs of IPT implementation sites; these were sites that were generally receptive to IPT and were already working with the technology, but often in an ad hoc way. NTAC brought a structured project management approach that enabled them to formalise the implementation of IPT. From an ANT perspective, the network of human and non-human actors was less complex in the IPT case, compared with the other two technologies studied in the research. Certainly, in the implementation sites, work had already been undertaken to address issues related to problematisation and interessement. However, the sites were lacking the guidance and 'know-how' to move further along the translation path in a systematic and structured way; the input from NTAC provided the support that these organisations needed. Through applying a project management approach and enlisting the involvement of key stakeholders, the NTAC model enabled and supported implementation sites to move through the translation path from problematisation/interessement to enrolment and mobilisation. Introducing IPT requires changes to the patient pathway and the design and delivery of diabetes services, for example in relation to patient and staff education and dedicated specialist nursing support. In turn, this requires a different set of networks and relationships to be developed. However, the fact that the evidence base for the technology was relatively well established and accepted (at least in the implementation sites) meant that the NTAC model of working had a good fit with the organisation's needs in terms of developing this new network of actors, agreeing and co-ordinating roles, and embedding new structures and processes required to sustain the innovation.

The data reveal a marked contrast between the experiences and views of the two implementation sites and the NIS, where the receptivity to the technology appeared more mixed, particularly in relation to the benefits of IPT, the evidence supporting its adoption and the feasibility of establishing a wider adoption programme. From an ANT perspective, it could be hypothesised that the NIS was still at the problematisation stage, with human actors (particularly the clinicians) not agreeing on the nature of the problem and whether or how it needed to be addressed. This site did not receive the type of external input and support that NTAC provided to address the translational stages from problematisation through to interessement and beyond. The existence of an online resource in the form of a HTWT guide did not appear to provide a comparable substitute to the more 'hands-on' role provided by NTAC to actively facilitate the translational process. However, the question remains as to whether or not the NTAC process would be sufficient to address the barriers in the NIS. The issues at this site appeared to be more to do with differences of professional opinion over the value and benefit of the technology, rather than more practical problems of how to ensure implementation.

# Chapter 7 Breast lymph node assay case study

## Introduction

This case study focuses on the adoption of BLNA, a diagnostic technology innovation[21] for the treatment of breast cancer patients. Its adoption brought changes to the patient care pathway – which were generally perceived by health-care staff to be beneficial – but also required changes in work practices that were not always easy to implement. It reveals the importance of local factors on innovation processes and the impact of PbR[12] on how stakeholders assessed the business case for adoption.

NHS Technology Adoption Centre selected BLNA for its HTWT guide programme in 2008. The evidence base for BLNA was considered strong and its adoption was consistent with the NICE guidance for breast cancer care:[206]

> *The National Institute for Health and Clinical Excellence (NICE) guidance for Early and Locally Advanced Breast Cancer (2009)[207] advocates that minimal surgery, rather than lymph node clearance, should be performed to stage the axilla for patients with early invasive breast cancer. The intra-operative analysis of sentinel lymph nodes offers the opportunity to streamline the management of breast cancer patients as part of a cohesive and comprehensive service, and according to a review in the* Histopathology *Journal (July 2009), this test is accepted as a reliable technique.*

NHS Technology Adoption Centre's own assessment of BLNA identified six key benefits:[206]

1. reduction in acute hospital admissions
2. reduction in overall length of stay
3. improved efficiency for the NHS
4. improved quality of life
5. higher quality services and support for patients
6. long-term savings for the NHS.

Hospital trusts across England applied directly to NTAC to take part in the implementation project in the spring of 2008 and, following a process of site visits and telephone interviews, six sites nationally were selected. Owing to unforeseen circumstances, two subsequently dropped out. A total of 34 interviews were carried out between March 2010 and September 2011 (*Table 5*). We also conducted participant observation of the final BLNA project awayday in January 2010, which was attended by representatives from each trust.

### *Mentor site*

The clinical lead at this trust had a long interest in the adoption of BLNA. The trust was the first in the UK to implement BLNA and was also a major contributor to a large national trial on sentinel lymph node biopsy. This experience led to the trust being selected by NTAC to become a MS for the BLNA project.

### *Implementation site 1*

The trust applied to NTAC to become an early implementation site in a project to introduce intraoperative sentinel lymph node biopsy testing. However, the application was rejected because of the breast care unit's limited track record of stand-alone sentinel lymph node biopsies. Instead, the trust was advised to become a 'How to Why to Guide implementation site'.

**TABLE 5** Interviewees for the BLNA case study

| Organisation | Number of interviews | Interviewees |
|---|---|---|
| MS | 5 | Consultant surgeon |
| | | Pathologist ×3 |
| | | General surgery manager |
| IS1 | 8 | Consultant surgeon ×2 |
| | | Breast care nurse |
| | | Pathologist ×2 |
| | | Pathology manager |
| | | Procurement manager |
| | | Operational manager for breast care |
| IS2 | 9 | Consultant surgeon ×2 |
| | | Breast care nurse |
| | | Biomedical scientist ×2 |
| | | Pathology manager |
| | | Breast care nurse |
| | | Procurement manager |
| | | Director of planning |
| IS3 | 10 | Consultant surgeon ×2 |
| | | Cancer clinical director |
| | | Pathologist ×2 |
| | | Breast care nurse |
| | | Pathology manager |
| | | Procurement manager |
| | | Operational manager |
| | | Data manager |
| PCT (for IS3) | 1 | Assistant director of commissioning |
| Community research group | 1 | Volunteer |
| Total | 34 | |

IS1, implementation site 1; IS3, implementation site 3.

### *Implementation site 2*

This trust provides general hospital services as well as highly specialist services. Its involvement in the BLNA project came about through one of the breast surgeons who heard about it at a professional meeting. Following discussions with NTAC, the trust applied and was chosen.

### *Implementation site 3*

This trust is a district general hospital providing a comprehensive range of acute and specialist services. The trust's initial application to be an implementation site was rejected by NTAC, but was subsequently accepted following further discussions with the then head of NTAC. One of the factors that influenced this was the trust's work to develop an in-house BLNA, which also reflects the fact that, unlike the other participating trusts, the adoption of BLNA was driven by pathologists rather than surgeons.

## Breast lymph node assay

Breast cancer affects more than 45,000 women each year in the UK. Under the established breast cancer clinical pathway, a patient diagnosed with breast cancer will undergo a mastectomy, during which the so-called 'sentinel lymph' node is removed and tissue sent for analysis. If this biopsy shows that there has been a metastasis (i.e. the cancer has spread to the sentinel lymph node), the patient will then be readmitted for a second operation to remove the remaining (axillary) lymph nodes. Apart from the additional psychological stress for the patient of having to endure a second hospital admission and operation, the current pathway can pose a clinical risk for patients as the cancer has further time to metastasise between operations.

Breast lymph node assay is a new test, the results of which can be ready within 30–45 minutes and so can be completed intraoperatively. If metastases in the lymph nodes are identified, surgery is extended to allow the remaining lymph nodes to be removed. Hence, the adoption of BLNA represents an improvement to the current pathway, in terms of both reducing hospital length of stay for patients and improving survival rates.[2]

## Getting started

At the project's initiation in 2009, a Strategic Steering Group was set up by NTAC to provide long-term strategic direction. This was followed by a series of awaydays where representatives of each participating trust (clinicians, histopathologists, nurses and procurement officers) gathered to be updated on the current status of the project and to discuss any issues related to its execution. At the final awayday in January 2010, particular emphasis was given to the current situation of the technology (and the implications of the withdrawal of the product being used, scheduled for August 2010; see *Dealing with technological uncertainty*), the HTWT guide, long-term strategic visions for the project and building up success stories related to BLNA adoption.

The afternoon sessions focused on the validation of the HTWT guide. Four working groups discussed the content of the guide and possible changes. Copies of the current version were distributed and participants given the opportunity to review its core components: data plan (to populate the business model); standard operating procedure for pathology; clinical evidence; procurement; and benefits versus barriers. Discussions focused on a number of areas, including the creation of new roles/responsibilities for histopathologists; the impact of BLNA on patient experience; and the standardisation of clinical pathways compared with local protocols. There was a general concern that the short time available to conduct the test would make the histopathologists' job more difficult. For some trusts, ensuring timely results would incur additional staff costs. Concerns were also raised about the psychological implications for patients of the 'one-step' rapid diagnostic test and instant clinical intervention.

For NTAC, this review exercise was essential in order to ensure that the guide was correct and in a format that was useful, practical and effective for the implementation sites. NTAC's goal was to progress towards the guide's 'sign-off'. In the event, the main obstacle to this was the guide's assumption of a standardised clinical pathway and, although the guide was eventually published, on the evidence of our subsequent interviews, this issue was never satisfactorily resolved.

## Understanding the benefits

Our evidence points clearly to the BLNA case study being an example of an innovation championed by clinicians. However, all the surgeons in all the participating trusts stressed that their support for BLNA was on account of the important benefits it would have for patients. In this respect, its adoption was a 'no-brainer', as one surgeon described it:

> *Well to be honest it was a no brainer, you've got reduced length of stay, reduced hospital visits, reduced anaesthetics, theatres, reduced surgeon's time … it was a no-brainer that if you could do this as a one-hit operation then that's what patients would want.*
>
> *Surgeon 2, IS3*

> *Because clearly that's good for patients because it reduces the number of operations. It's good for clinicians because they get a result quickly, and it's good for the people who are paying our bills because they see a saving … So the clinical argument was won inside a matter of an hour when I presented the business case.*
>
> *Director of strategy and planning, IS2*

> *The key thing that is the advantage to the patients is avoiding a second surgery, a second anaesthetic. That is a key advantage of this procedure. So, even though we were concerned about time and theatre space and number, because it has reduced the number of patients we do per list … I think we, as a team, have decided that the patient comes first … before we started intra-operative testing, up to six weeks to find out what is the ancillary staging would have taken up to six weeks.*
>
> *Surgeon 1, IS3*

However, clinical staff did have some concerns about the new consenting process that patients would have to taken through. A surgeon observed:

> *The patient's consent has to be careful because the patient is consenting for a sort of either/or option and therefore consent can be arguably a little bit difficult, because you're saying to a patient, we're going to do this, if it's positive, we'll do your axilla and if it's not, we won't and therefore there's an uncertainty. The patient's going to wake up with an uncertainty. The first thing they're gonna say to you is, was my axilla clear?*
>
> *Surgeon 2, IS3*

Although surgeons accepted that the consenting process would need to be amended, they did not anticipate it would be difficult for the breast care nurses to implement; the latter, however, had a different view:

> *I think what we haven't thought through with this technique is how we support patients is we've seen it as great that we get earlier results, great that we don't have to re-admit patients to come back and have ancillary surgery but we haven't thought about the impact for the patient … at the moment there's no information leaflets, there's no plans or processes to support it … The patient will go to sleep with uncertainty about what they will wake up to. So for some they'd have had their lymph nodes removed and some they won't … So that nobody really had a lot of consultation with her about that dread that she felt when she woke up.*
>
> *Consultant nurse, MS*

A breast care nurse emphasised the need to consider the psychological impact of patients, reinforcing the sense of divergence in understanding of the challenges among surgeons and nurses:

> *Yes as you say, it is really for them, the uncertainty of, you know, will the test come back showing that I don't need to have any lymph glands removed, therefore, you know, my cancer is not as bad as it could be. Or if they come back positive then, oh dear my cancer is, you know, as bad as it can be in*

*their minds. And it's the psychological impact of that. And they just knew that if they had that drain there, that's what had happened.*

*Breast care nurse, IS3*

On this evidence, it became apparent that patient acceptability might be a significant problem.[68] Acknowledging this, the clinical lead at implementation site 2 (IS2) proposed that it could be resolved through providing patient information:

*The patients would be happy to be offered a one-stop operation rather than the possibility of two. What we don't know is how our patients will take this because they know that when they wake up and they have a drain you know that their lymph nodes are positive … so what sort of psychology it will throw them into we don't know so if two people come for the same operation … So what we're going to do is offer some pre-operative information giving that the important thing is to have a one stop operation rather than a two stop operation and if it's positive of course it can be treated. At least we know what it is. So that's the only tricky side but we have patient information for that.*

*Clinical lead, IS2*

However, further investigation by breast care nurses convinced them that leaflets would not be enough by themselves, a conclusion that ran contrary to NTAC's expectations and would have implications for the business case:

*I wanted to know the specific psychological needs of the women who'd had the assay and woke up to find that they'd had their lymph nodes removed as well because the assay was positive, to make sure that we had the correct service with the resources to offer the care that the women needed. And previously, when I'd been to an NTAC training day in Manchester, there all of the staff said that there was no additional resources needed, breast care nursing wise … but when I actually went to [Mentor site] it was very different. The ward nurses told me that they'd all worked on a dedicated breast ward for many years, were very experienced, and they found it very hard to deal with the women, the first day post-operatively and often had to call the breast care nurses over to support the women because they didn't feel that they could do it adequately. And then speaking to the breast care nurses, they could demonstrate that they were regularly called to the ward, just out of the blue, for extra support that they needed to give the women. So I then, you know, realised that I needed to put in a business case for some more breast care nursing hours.*

*Breast care nurse, IS3*

It should also be noted that, as even the strongest advocates of BLNA adoption acknowledged, the intraoperative test is not as reliable as the 'gold standard' post-operative test, in terms of numbers of both false positives and false negatives. Hence, the post-operative testing would have to be continued and some patients might find themselves undergoing a second operation despite the initial, intraoperative 'all clear':

*The problem is of course histology is the gold standard, you always have to do that, you always have to use the gold standard, as what passed before. So it's called a false positive or a false negative, where it's probably, and it has happened of course when histology has found a micro amount that we didn't have because it was in the slice sent to them, and not been put in our slice … Obviously if histology do find a positive then the patient can still come back and have the further surgery … and it has happened, there's been about four cases I think where, I don't think they necessarily brought the patient back each time, because they were micro amounts, I think in some cases they just treated with radiotherapy.*

*Biomedical scientist, histology, MS*

Again, the costs of running two tests would have to be accounted for in the business case.

## Making the business case

In any organisation, management decisions on the adoption of a new practice will be influenced by its financial implications. Hence, the first hurdle to be overcome by the trusts involved in the BLNA project was to gather the evidence and make a business case for its adoption. Once compiled, typically this would then have to be prioritised against competing business cases:

> *So we started to work up the business case for the inter-operative analysis alongside other business cases for breast care. And that other big business case was around the reconfiguration of the outpatient department to make the service much more efficient, to actually look at how we could do parallel clinics … we actually were successful with the business case for the reconfiguration of the unit because we could see that that would make some financial benefit, but also it would actually improve patient experience because we could run parallel clinics. The one that didn't go forward was the intra-operative assessment analysis, and that's the one that we're putting forward this year … Because there's only a finite amount of money … and that scheme was not given priority … It would be quite surprising to get support for more than one big business case actually in one directorate.*
>
> *Operational manager for breast care, IS1*

One reason why it might not get prioritised was because, financially, BLNA presented considerable risk to trusts that chose to adopt it. Most obviously, this risk arose from the apparently inequitable distribution of the overall reduction in costs that BLNA was capable of delivering: put simply, under the PbR regime, the commissioners (i.e. the PCTs) stood to gain from the reduction in bed-days and theatre time, whereas the providers, the trusts, stood to lose income for the same reasons. The difficulties of making a business case in such circumstances were acknowledged by clinicians:

> *For all it's said to be a cost neutral exercise, in that one isn't more expensive than the other, the trust actually loses money in that they don't get the income from the second operation anymore … it does mean that from a financial point of view and a service provision point of view … there may be some reticence from a hospital to lose income, even if it's also less work.*
>
> *Consultant breast surgeon, IS1*

> *This is what this is about; it's a two-way process here. It's about some of the issues that I have in presenting a robust business case to get this forward. So there are lots of things that we all recognise is best for patients – there's no doubt about it – but it's trying to actually recognise the revenue consequences of this and the potential loss of income to the service as well … so … I have to actually argue it from a patient experience point of view, you know, but also from a financial point of view. So it's trying to join those up.*
>
> *Operational manager for breast, IS1*

One strategy was to look for savings elsewhere, but this was not an easy task:

> *But actually, as a pragmatic business manager, you have to say that if this is going to cost you more and you're losing income, which you are with this case – there's no doubt about it because these patients would be coming back in or some of them would be coming back in for a second procedure – the cost of it is more because the assay alone is £250 a time, plus all the lab costs. Everything is going to cost you more to run this. So the only way we could take that hit is either to get more money from the commissioners or to make savings within our own department to offset the cost. And that's the difficulty we have; how can we identify savings to support this?*
>
> *Operational manager for breast, IS1*

The lack of a national tariff for BLNA was identified as the underlying obstacle to trusts and PCTs being able to agree to adopt it:

> *What we did have to do was put a business case together for the Checklog system and convince the trust's Planning Committee that that was a good idea. Clinically and financially. In fact I think they got their sums wrong and we probably shouldn't have been doing it! What I hadn't realised was that saving the NHS money did not necessarily save the trust money. It saves the PCTs money but the PCTs don't pay that money to the trust so the trust actually loses money. It is much better for the trust to do two operations rather than one because they get two tariffs. Which is one of the crazinesses.*
>
> *Pathologist, MS*

Not surprisingly, the potential for a financial conflict of interest between service provider and commissioner was seen as being contrary to patient interests:

> *Throughout the Health Service there's no global view. Every section has to worry about its budget so that if one section saves money for somebody else they may be penalised but the other section benefits, whereas what actually matters is that the patients are getting a better service and potentially saving money as well.*
>
> *Lead pathologist for breast pathology, MS*

So, unless some sort of arrangement could be reached with the PCTs, the trusts might find the implementation of BLNA unsustainable:

> *From what I've seen a lot of the barriers though are purely financial, the arguing between PCTs and who's going to fund this and yes you're saving theatre slots but what are you going to fill them with and we'll have to pay for more operations.*
>
> *Biomedical scientist, IS2*

This problem could only be resolved through negotiation between the trusts and their PCTs of a local tariff or pass-through payment. Much would then depend on the relationship between the trust and its PCTs. At IS3, this did not prove to be an obstacle:

> *And we came together with well what on earth, there must be a mechanism under the tariff in some way of introducing an incentive to put this in place … a pass-through payment… What happened was our finance person contacted the strategic health authority who contacted the Department of Health to find out how we could work this, because I think initially for us in the first year it was going to be more expensive, but less expensive year two, three, four and five. So we had to justify that. And it is called a pass-through payment. And it is to do with innovation. I can't remember how it worked.*
>
> *Assistant director of commissioning, IS3*

Implementation site 1 (IS1), although it had a good relationship with its PCT, perceived that negotiating a pass-through payment would be difficult:

> *I would say we have a good relationship with our commissioners, but we all recognise that we're not in a time of plenty … So it's about trying to do the best you can with the limit you have … The best outcome would be if the commissioners said, 'Yeah, we recognise it's best for patients. We accept it's a cost pressure to you. We will give you a local tariff,' which is over and above what we get for PbR, then we'd be fine … But it's not going to be that easy because the commissioners have an efficiency target to meet as well and, you know, they've got lots of other services that are coming to them in the same way with innovation.*
>
> *Operational manager for breast, IS1*

The unpredictability of the outcome of local negotiations between trust and PCT was an obvious obstacle to trust managers, who questioned the lack of push for innovation at a national level:

> *You know, so why isn't there a dialogue at a national level between the PbR national guidance around tariff and innovation? So if you could have done that in the very early stages to say this is a new innovation, you know, we recognise it costs more than the current one but the patient experience is so much better, if it would actually come with a new tariff, then, actually, you'd be halfway there … I think if it were more joined up and if the innovation came along with guidance around how you could maximise your income through an appropriately agreed national tariff recognising that innovation, then it would save any issue and any dialogue with the commissioners locally because it would be very clear that this was a worked up clear cost of this procedure and the benefits would be recognised as well. So definitely … it would reduce the barriers.*
>
> *Operational manager for breast care, IS1*

Loss of income was not the only financial challenge faced by the trusts. All trusts faced having to make a significant capital investment in assay equipment (for which the favoured solution seemed to be breast cancer charity support), training for pathologists and, in some instances, refurbishment of accommodation for the equipment and pathologist. Recurrent costs included the purchase of reagents for the test. In addition, there could be additional staff costs. As noted earlier, more breast care nurse time was needed for counselling patients and, in some trusts, the recruitment of additional pathology staff would be needed to cope with the increased workload:

> *And staff as well, I mean we are without a doubt having to struggle badly for staff when this gets implemented, 3 days a week with a qualified member of staff out to satellite lab all day, it's going to hit us hard.*
>
> *Biomedical scientist, IS2*

These various financial factors combined to make the creation of a credible business case challenging for some of the trusts involved. For the MS, however, it seemed that a different culture prevailed. Here, the adoption of BLNA was spoken about as being consistent with the trust's vision to become 'a world class hospital', whose pursuit required an active approach towards innovation:

> *I think one of my roles as General Manager is to kind of unblock that inertia and actually encourage people to come forward with ideas and innovation.*
>
> *General manager, MS*

In the view of the MS clinical lead, this research culture was under threat and this would have repercussions for innovation in the NHS:

> *The history of innovation is that it tends to happen within very large hospitals with lots of academics … If you lose your academics … you lose the ability to innovate because you've lost the people who will do it. And the people that are left are not paid to innovate, they're paid to push patients through the door. Many of them are highly intelligent individuals who would like to innovate but the moment they come up against the hurdles that are put in their way in terms of committees and requirements to go and sort out things and, the treacle is such that you just don't start.*
>
> *Clinical lead, MS*

## Dealing with technological uncertainty

Breast lymph node assay adoption was surrounded by uncertainty around the supply of the necessary technology. Initially, two different commercially available systems were selected for improved detection and analysis of breast lymph nodes: Orglog, a technology which uses a Japanese technique known as one-step nucleic acid amplification (OSNA), and Checklog, a technology (US-based company) using the technique of quantitative reverse transcription-polymerase chain reaction. Both rely on an existing procedure known as a sentinel lymph node biopsy, a selective but accurate method where tissue is surgically removed and sent to a pathology laboratory for tests. The MS chose Checklog. The implementation trusts were testing both technologies in order to decide which to adopt.

At IS1, the decision over which technology to choose was taken by the lead clinician who would be responsible for the BLNA service in the trust. As the laboratory manager for cellular pathology explained:

> *It was based purely on what was recommended as he's the surgeon. So he would have to be happy with the results and it was his decision which one we went on … I don't know, that would have to be up to our procurement department. Again, which is – I don't have much input into it. Because my role in it if it had happened would be to provide the technical support. The interpretation of the results were going down to the surgeon, so he had to be happy with whatever process was in place. And therefore I left it very much up to them to decide what they wanted to do, and my job would have been to literally do the tests and make sure we have the money in the budget to cover it.*
>
> *Biomedical scientist, IS1*

However, while the trusts were, in some cases, still deliberating on which system to choose, Checklog withdrew its product (DNAseek) from the market in August 2010, citing financial reasons, leaving trusts favouring this system with a major problem. As no intellectual property rights were in place, trusts favouring the Checklog system would have the option of developing equivalent systems in-house. IS1 was interested in adopting the Checklog system as it had already concluded that it was superior to Orglog.

> *We knew that [xxx] had been doing the single probe technique … So we knew that was available. But we thought that the two-probe technique, the Checklog one, was superior. In fact, we had some meetings with the Checklog representative. We'd had those meetings before the bid from the HT [NTAC] came in because we'd heard from the research side that this was a new technique, and so we'd engaged with the Checklog representative. So we were aware of it, but we'd built the business case around the Checklog rather than the OSNA one, which was, in retrospect, probably not such a wise idea because we didn't know [large company X] were going to pull out.*
>
> *Consultant breast surgeon, IS1*

For those trusts not in a position to provide their own version of the now unavailable test, the option was to go with what (for some) was the second choice technology:

> *… [Mentor site] is unusual, it's very well staffed from a pathology point of view and also it has its own molecular unit, you know, which is fairly unusual, and we have nothing like that. So … they are able to continue with their existing expertise and their existing machinery. And one or two other places, a couple of other places, have linked up with them to keep what I think essentially is the DNAseek system going, even though that's now withdrawn and the consumables are withdrawn, they've been able to produce their own consumables. We are unable to do that. That's because we don't have the technical expertise and certainly our laboratory manager says they're not going to do it and it's a technical function rather than a medical function anyway, so, I mean, I wouldn't actually push them to do that. I don't think they're capable of doing it.*
>
> *Consultant histopathologist, IS1*

Implementation site 3 (IS3) had also initially selected the Checklog system, having rejected Orglog because of its perceived failings. However, unlike IS1, it had the skills needed to develop its own in-house assay and, at the time of interview, this was in the process of being validated:

> *… mainly because the commercial assay has been withdrawn, there isn't an assay available at the moment apart from the OSNA system. The OSNA system has major failings, major failings on the basis that it's a single-marker assay at the moment, there is no internal quality control.*
>
> *Pathologist, IS3*

## Reconfiguring clinical workflow and practice

Successful adoption of BLNA would only be feasible with adaptations being agreed in the clinical workflow and in the working practices of trust staff. How significant these adaptations would have to be depended on circumstances at each implementation site. As a consequence, for some sites, this necessitated a lengthy series of negotiations between the different staff groups involved – surgical teams, pathology and nurses[64] – and this impacted on the making of the business case:

> *So I guess the complication with this is that you're working with the labs and you're trying to pull the business case together for lots of different factors, whereas generally, as a business case, you'd write it for yourself and your own department. You're trying to sort of pull it together from all different areas.*
>
> *Operational manager for breast, IS1*

For pathology laboratory staff, these changes included having to learn a new procedure against a background of increasing complexity of their work:

> *Yes, complexity of work is increasing constantly. When I started, a typical mastectomy for breast cancer might have five paraffin blocks of tissue taken with an H&E on each one, now well [xxx] will be able to tell you more exact figures about the kind of blocks and complexity on the breast work, but it's what, 20 plus blocks?*
>
> *Biomedical scientist, IS2*

In the case of Checklog system (before it was withdrawn), pathologists at the MS received training from the company, a factor that helped smooth its adoption.

Most notably, pathology staff would now have to be available to do test tissue samples on demand, a change that increased the pressure on them in two ways. First, the test had to be completed within a short time frame, which meant that a pathologist had to be available but also meant that they needed to get the sample to pathology with minimum delay:

> *… the big thing for us is we knew it was going to be a high pressure test with a lot of pressure on a biomedical scientist to provide that result accurately and quickly with a surgeon banging on your door.*
>
> *Histopathologist, IS2*

Where pathology was in the same building as theatre, this was not a problem but this was not the situation at some trusts. For the latter, one solution was having runners available in the pathology laboratory to collect samples from theatre as soon as they were ready. Another was to have the pathologist assigned to BLNA testing located close to the operating theatre suite.

At the MS, this was not a problem as space was available next to the theatres:

> *We had space to set up the laboratory next to theatres there, so one of the things that has been different about us is that we've always had this done in theatre.*
>
> *Pathologist, MS*

At IS2, this meant adapting a room close by for pathology use, Of course, this had cost implications:

> *… there's a room identified … that can be used yes so that's why we are going to build, well they have to remove this and make it into a proper lab yes and that is going to cost about £14,000.*
>
> *Clinical lead, IS2*

A consequence of physically relocating the assigned pathologist close to the theatre was that the pathologist would be deprived of the support of colleagues that they would normally be able to call on when faced with a difficult diagnosis, thereby increasing the risk of error:

> *… there will be a single band 6 or band 7 biomedical scientist isolated away from their colleagues in a room with a surgeon wanting a result. They've got no, here, if you're struggling with a frozen section because it's difficult to cut you can call on a colleague, maybe somebody more experienced, can you come and have a look at this and help me out. There, you won't be able to do that, you will be isolated and that's, to me is the real difference …*
>
> *Histopathologist, IS2*

Finally, dealing with the new procedure raised concerns that pathology staff at some trusts would be unable to carry out their normal workload while they are testing the assay, and hence would demand recruitment of additional staff, further escalating the cost implications.

The other significant area where adaptations in working practices were called for was, naturally enough, in theatre. Extra time would be needed when the BLNA assay was positive in order to do the axillary clearance, making the management of theatre lists more complicated. However, although this was widely anticipated by surgeons and theatre staff, how these changes should be best managed was a matter of continuing debate and, to some extent, trial and error, and would not be fully understood until the new procedure was introduced. The problem essentially was one of theatre list management and, specifically, accommodating the extra procedures (and their effect on operation time):

> *Theatre planning, in terms of advance planning we don't know how much of that theatre capacity will be needed. Like any organisation we're trying to reduce our costs, which means we're trying to get a better throughput in theatres, this conflicts with that slightly, in terms of having to allow the flexibility to, to have an extra 15 or 20 minutes on the session for each of these procedures, not all of which would be used … the figures I've got is 28 to 30 per cent would need the further surgery.*
>
> *General manager of surgery, MS*

He went on to explain the additional complexities of theatre planning introduced by BLNA:

> *So there are going to be some patients that will need the clearance, and others won't, so what are we going to do about that? How do we plan theatre time to make it as efficient as we are now because we expect to be running at, at least, a minimum of 90 per cent efficiency? … How do you plan a list when you don't know if a woman's going to be on the table for another forty minutes? And I know the consultants say they can do some other work, but it's still not going to make efficient use of the theatre if they're carrying on doing other things.*
>
> *Operational manager for breast care, MS*

Given the concerns over the implications of BLNA for efficient theatre utilisation, getting theatre staff on board was perceived as the biggest barrier for some of the participants. As a consultant pathologist at the MS commented:

> *It became very difficult to get theatres to agree to go live, to actually start acting on our results … because if the result is positive, then further surgery will ensue, this could go on for another half hour to an hour, if you have three cases on the list, and we do, in fact we've had four, if they're all positive then that list is going to overrun … That was my biggest barrier, was getting the theatre staff on board. Once they were, that was it, plain sailing, you know, we've not really looked back.*
>
> *Biomedical scientist, histology, MS*

Various adaptations to theatre procedures were being experimented with as a way of mitigating the knock-on effects of additional surgery:

> *It's 40 minutes longer anaesthetic and it's 40 minutes for the surgeon to twiddle their thumbs and surgeons don't like twiddling thumbs. So we … we work that round is that the sentinel node is the first thing that's done, so you go in, you do your sentinel, you send it off and then you tackle whatever breast pathology you're dealing with from the breast, whether that be mastectomy.*
>
> *Surgeon 2, IS3*

One approach was to assume that test results would be negative and to 'close up' patients while waiting for the result:

> *So we're actually already closed up and then we're just waiting and usually it's another five minutes once you've done that, just waiting for the phone call. The phone call comes, negative, wake the patient up. The drip is already on, the stitches … the wound's already closed, bang, gone. If the phone call says it's positive, then basically just get gowned and gloved, the registrar's there, takes the dressings all down, cuts the skin and stitches back, we're straight back in. You do the clearance, you're adding another 20 minutes, half an hour for a clearance on top.*
>
> *Surgeon 2, IS3*

However, such 'in surgery' workarounds could not be guaranteed to be foolproof:

> *You get the list and there may be two sentinel lymph nodes on there, [say the] first and second cases and you know you think: Excellent, send the person over and then they can come back when they're finished. But something happens and for some reason, either the patient's cancelled or they get pushed down the list and then you've got the person waiting over there to do the assay not doing anything else and of course if they get pushed down the list then it's basically wasted time.*
>
> *Consultant histopathologist, MS*

> *[If] it finishes late then you've over utilised your list and conversely if you've got three patients on and you're expecting one of them to be positive and none of them are positive you may underutilise your list so there are you know its swings and roundabouts.*
>
> *Consultant breast surgeon, MS*

Hence, a question that preoccupied the surgical teams at each trust was how best to organise the theatre list to accommodate the possibility of a patient requiring a second procedure while limiting the disruption to the list as a whole. The exact solutions they came to varied between the trusts, though most were using a similar technique, based on trying to predict which patients would be more likely to test positive for spread of cancer and using this to order the operating list.

At IS2, the surgical team had developed heuristics that they believed would enable them to anticipate – and, hence, mitigate – the impact:

> *If somebody has a high risk tumour, a grade three tumour which is large it is more likely that they are likely to be positive than somebody with a smaller tumour which is grade one or grade two. So you will want to leave the grade three ones towards the end of your list rather than, because if you do the grade three ones in the beginning and then it's positive then you're going to spend more time doing your list by about an hour.*
>
> *Clinical lead, IS2*

A similar procedure had been discussed at the MS but not, as yet, adopted:

> *In Cardiff it was being used … there was talk about stratifying patients as to in their risk groups as to how likely the patients were to be positive or negative and then planning this [theatre list] appropriately.*
>
> *Consultant breast surgeon, MS*

Other factors to be taken into account in theatre list management emphasised how the success of BLNA depended on a closer co-ordination between theatre and pathology teams, in that the hours in which pathology staff would be available could not be assumed to extend over the whole of the time it might take to complete a theatre list:

> *And also you want to do it within time because the pathologist maybe has to leave at five o'clock so you don't want to leave your last sentinel lymph node later than four o'clock. So you want to do that within time and this procedure has such a crucial working relationship with the pathology department actually.*
>
> *Clinical lead, IS2*

Hence, the solution adopted by one trust was to schedule patients judged likely to require a second operation at the start of the list:

> *It does, it just means trying to get to a new optimum way of working and trying to use a proper sensible basis to try and predict what is likely to happen and tailor your list accordingly.*
>
> *Clinical lead, IS2*

However, theatre staff would always have to be ready in case things did not go according to plan. In extreme cases, there might even be a need to cancel an operation if time was running out, but this risked disruption to wider theatre list planning, quite apart from the stress and anxiety inflicted on the patient.

The final element of the impact of BLNA adoption on work practices concerned the role of the breast care nurses in dealing with patients and also had cost implications:

> *But the breast care nurses would like to be there for the patient when they're waking up so that, you know, they're waking up and they know the prognosis is not so good, but they've got someone who they know and who has some expertise. And so that's time and money for the breast care nurses as well.*
>
> *Consultant breast surgeon, IS1*

Not surprisingly, given the above, those championing the adoption of BLNA found making a business case a difficult proposition and one that, in the case of the implementation trusts, the HTWT guide did not necessarily prove to be of much assistance.

## NHS Technology Adoption Centre and the How to Why to guide

Several interviewees at the implementation sites remarked that the HTWT guide had been of little help in tackling the hurdles that they faced in getting approval for BLNA adoption and they did not expect it to be of much assistance elsewhere:

> *Well, the business case is normally written by our manager with advice from ourselves. So I provided the information from the How To Guide and the empty boxes that you have with it suggesting that they fill in the numbers around our case. But they felt that that didn't mesh with how business cases are submitted within this trust. You couldn't just paste the How To Guide … And so that sort of didn't progress.*
>
> *Consultant breast surgeon, IS1*

Discussing the value of the HTWT guides, the operational manager for breast care at IS1 commented:

> *And that's the problem, you see. All the arguments that they give for bringing this in except, you know, the patient experience – are all the issues I have and it doesn't tell you how to overcome those issues … It was just a reminder. I mean, actually, most managers, if you're used to writing cases, would be able to know how to be able to write a business case. And obviously each organisation does things differently, but it actually just reminds you of what you should be considering. But if you know your service, probably the information – It's just a confirmation really. I didn't find it useful. I didn't learn anything from it because it actually didn't give me the answers to my own problems locally. And the things that they suggested, I already knew. So it was more difficult.*
>
> *Operational manager for breast care, IS1*

One specific issue raised by the participants in the implementation trusts was the collection of evidence that the guide stipulated would be needed to underpin the business case. This was a problem because the data required were not routinely collected and doing so would demand a significant effort which the trusts could not resource:

> *[xxx] wanted some data, the breast surgeons told him they didn't have access to it and he sent an email to me saying, surely you must be able to get this data, it's easy and essentially it wasn't easily because we don't routinely keep that data. It was how many … positive nodes wasn't it, they wanted a number putting on that, so that would mean like reading through 300 patients.*
>
> *Biomedical scientist 1, IS2*

> *Reports for every mastectomy, wide local incision, so I said, well if you've got the staff, send them, come and look through them, feel free, we haven't … And there was a move afoot at that meeting where they want to collect as much data as they possibly could and set up centralised data collection. One trust, one site would be responsible for collating all this data.*
>
> *Biomedical scientist 2, IS2*

Crucially, NTAC was criticised by some participants for not having involved PCTs in the development of the BLNA guide:

> *And I thought right from the outset, when we put in our application, it was absolutely key to have your commissioners on board with you on the project right from the start. And I think that, again, we were fairly unique within the group when we went – when we had our first NTAC awayday, the others all sat up when they saw [xxx] there. They said god, why didn't we think of having a PCT lead on our project straight away, because I mean let's face it, they're the people that are paying for it. So, you know, you've got to have them on board, engaged in what you're trying to achieve right from the start.*
>
> *Clinical pathologist, IS3*

Overall, participants acknowledged that being involved in the BLNA project had brought advantages. It had created the opportunity to work with staff from different trusts, had enabled comparing of practices and exchange of ideas about solutions to problems:

> *I think the premise of NTAC is very good for getting different areas within a trust, the clinicians, pathologists, pathology staff together whereas otherwise they might have never of had a meeting, oh no I can't do that, you know how these things work but because they were being pushed into it externally it's more likely to actually happen and then also you'd got those groups of people that were then forced into meeting and working together within the trust, being forced into meeting and working with similar groups of people from other trusts as well.*
>
> *Biomedical scientist 2, IS2*

However, there was scepticism that this mutual learning would have any transferable value for trusts in dealing with what many perceived as the major stumbling block for BLNA adoption – the lengthy and difficult negotiation process between trust and PCT:

> *I think the aim if I've understood it correctly was that by the four pilot sites doing what they did they would end up assessing a new technology which for anybody else that wanted to take it up and run with it all they had to do is to pick this up, take it along, get it agreed and you could roll the technology out very quickly; and I agree that that is a laudable aim … I just don't see having been through the process on several occasions you know with business cases, it always seems to come down to those local negotiations that are going to go on between the PCT and the trust and that in reality is what's taken the time to get sorted out.*
>
> *Directorate manager of pathology, IS2*

> *I think we could have achieved what we needed to achieve anyway. What did come out of it from NTAC was hopefully a guide to others as to what they were going to have to go through which I think will be a useful guide but I'm not sure that that is going to stop the same problems that we've experienced because you're still going to end up with the same negotiations, the same discussions with a different set of PCTs … it isn't going to stop the interactions that have to be gone through with the PCTs and the organisation.*
>
> *Directorate manager of pathology, IS2*

With respect to the HTWT guide specifically, concerns were expressed that the low level of awareness of NTAC and its activities would blunt its value:

> *I don't think a lot of people have heard of NTAC. People have enquired about the assay, I've pointed out the guide, and it doesn't seem to be that anyone's heard of it or known they can access it, so there's definitely a problem it's all been very worthy stuff … and then hardly anyone in the NHS even seems to know it exists. They need to get a higher profile really.*
>
> *Biomedical scientist, histology, MS*

## Discussion and summary

The adoption of BLNA was arguably the most complex of the three case studies we undertook and this clearly impacted on the speed with which the implementing trusts were able to complete their projects and, because adoption was contingent on local factors, it also impacted on the *way* in which they went about it. Yet, at the start, the prospects must have seemed good, the basic case for adoption was strong and, when looked at from the perspective of the NHS as a whole, unambiguous and adoption was consistent with NICE guidelines for breast care. As we also saw from the interviews, clinicians were unanimous about the patient benefit and their role as organisational champions clearly made a difference.[72] However, staff who had direct contact with patients (i.e. breast care nurses) were not so

confident that patients would be able to grasp this when they were already likely to be experiencing anxiety and pressure.

The complexity of the BLNA case study arises from a number of organisational factors[78] that came into play at the trust level (i.e. financial implications and risks;[58] adaptation of clinical workflow and reconfiguration of surgical and non-surgical work practices,[73,119,121] some of which required negotiation across professional groups;[64] and technological uncertainty). Of course, it is these trust-level challenges that HTWT guides are designed to tackle, but the effort of translating a generic template for innovation so that local factors could be taken into account was time-consuming. Making a case for adoption demanded significant effort if trust management – and other stakeholders – were to be convinced that this could be done within acceptable levels of risk – financially and operationally. Trust management also had to weigh up the relative benefits of different service development options and possibly prioritise them.

From a financial perspective, PbR meant that trusts might not themselves experience the benefits identified by NTAC, at least in the short term. To add to the challenge of making a business case, there would also be costs of equipment and staff training. To help with the presentation of the business case, HTWT guides include a business model template that set out in a standardised, tabular format the key elements to be addressed. Reflecting the complexity of the BLNA business case, its HTWT guide also included a costing model to help trusts estimate the financial implications of implementation. We found no evidence, however, that it was used by the trusts participating in the BLNA project.

At the clinical pathway level, reorganisation of theatre lists was necessary as the intraoperative testing has the potential to cause both under-runs and over-runs of theatre lists. How this reorganisation would be done would vary from trust to trust. In addition, for some trusts, these changes could result in additional costs, for example the recruitment of new staff or the provision of laboratory space close to the theatre. Service level adaptation was required not only for breast cancer surgery itself, but also for outpatients, follow-up clinics, bed use on main wards and other services which shared the same facilities.

A key area of non-surgical work practice reconfiguration was in pathology. The need to train pathology staff in the skills required to perform the assay was relatively easily satisfied. Trusts found it less easy, however, to meet a core requirement – rapid testing and reporting back of results. Ideally, the assay would be done in theatre, in an adjoining room or, at least, in the same building. However, not all of the trusts could satisfy this requirement without making significant changes to pathology work practices (e.g. creating a new 'satellite' pathology laboratory next door to theatre; using 'runners' to take the biopsy to the pathology laboratory and return with the results, which added to costs of implementation). Moreover, as a histopathologist would now have to be 'on-call' whenever a breast cancer surgery list was scheduled, there were concerns that pathology staff would be unable to carry out their other duties at these times. Pathology staff themselves expressed reservations about the impact of time pressures and, in some cases, isolation from other laboratory members on the reliability of results. The workplace studies research literature on the importance of colocation for informal collaboration and the role of the latter in the routine achievement of dependable work in medical and other work settings (see, for example, Luff *et al.*[208] and Buscher *et al.*[209]) substantiates their concerns about the risks involved.

Finally, the BLNA project was affected by uncertainty around the supply of the technology. When the project started, supply of the technology appeared secure, hence NTAC would have had no reason to see this as a risk factor. By the time one of the suppliers withdrew, the project was well advanced and the trusts were able to adapt. However, this contributed to delays in implementation as the pathology labs re-evaluated their options.

In summary, the barriers faced by the trusts participating in the BLNA project can be attributed to a range of factors: funding issues (i.e. financial reimbursement mechanisms, paying for additional pathology and nursing staff); the reconfiguration of services in order to fit with new clinical procedures (i.e. surgical lists, bed use, reorganisation of pathology work to ensure good access to testing facilities from operating

theatres); user training and acquisition of new skills (i.e. for pathology staff); and uncertainties about the availability of the technology itself. In ANT terms, they can be understood as outcomes of complex interactions between heterogeneous networks of human and non-human 'actors'.[84,88,89] In the BLNA case study, we can identify two key groups of human actors: trust staff (clinicians, pathologists, nurses, business managers) whose alignment is needed to adopt the innovation, and PCT commissioners, with whom the trust must negotiate how the adoption of BLNA will be paid for. For BLNA, the evidence base furnished by NTAC was effective in achieving *problematisation*, the first stage of 'translation', but subsequent stages of *interessement* and *enrolment* proved more difficult and contingent on local factors, so that each trust came up with its own solution. First, supporters had to negotiate the prioritising of competing business cases. Second, uncertainties over the availability of the technology had to be resolved and changes in working practices demanded by its adoption agreed upon.

Financial risks mean that business managers might not be convinced that adopting BLNA was in the trust's best interests. However, as we saw in the case of the mentor trust, where a trust has a strong research culture and reputation to maintain, other factors come into play and tip the balance in favour of adoption.[49] However, there was concern that this research culture was under threat from increasing bureaucracy. Of course, without some trusts being in a position to offer mentoring in innovation, the NTAC model cannot work.

For the participating trusts, the BLNA project had had real benefits. Attending the awaydays enabled staff members to compare practices, to extend their professional networks and to engage in 'social learning'.[73] However, what was unclear was whether or not there had been useful learning that could be 'packaged up' in the HTWT guide for reuse by others in the future, that is to enable other trusts to overcome the barriers and follow the translation process more easily through to successful completion.[45] In other words, the HTWT guide was seen as providing a template for innovation at only the most generic level. In ANT terms, the guide was a useful tool for *problematisation*, but of more limited value for *interessement, enrolment* and *mobilisation*. In the absence of a central push for innovation that would drive this translation process, its value would inevitably be limited. No information is available to us about the subsequent use of the guide by other trusts.

Even if there were a stronger push on trusts from the centre to innovate in the NHS, the BLNA study demonstrates that financial instruments such as PbR would still be a major impediment to securing the interest of all key actors and persuading them to co-operate.[19,52] The impact of PbR makes itself felt when the costs of innovation cannot be contained within the boundaries of the health-care provider (trust) or commissioner (PCT) and a national tariff for the innovation does not yet exist. In the absence of a national tariff, adoption of an innovation such as BLNA by the NHS will depend on local factors, in particular a willingness on the part of service commissioners to find an equitable solution to sharing the costs and benefits. However, when this does not happen, for an innovation like BLNA, it creates a major obstacle to the achievement of *mobilisation*, the final stage of translation and its adoption across the NHS.

# Chapter 8 Discussion and conclusions

In this chapter we first return to our research questions, using these as subheadings to organise discussion of our findings across the UFRI, IPT and BLNA case studies. We next consider our findings in relation to our aims and objectives. To begin this discussion, *Table 6* summarises the main characteristics of the three clinical technologies under discussion.

Of the research questions, four are specific to NTAC. We considered NTAC's role in *Chapter 4*. In this discussion we further consider its function in relation to the three cases. We consider the final question about best practice for technology adoption in our concluding comments.

## What are the main organisational and decision-making processes and challenges specific to the adoption of the project technologies? What are the barriers and enabling factors?

When any trust is considering the adoption and implementation of a clinical technology they will be concerned about clinical efficacy and utility. Madden[48] points out that there are sometimes disputes over how medical devices (including clinical technologies) are best evaluated; she reports that practitioners argue that greater reliance should be placed on the 'real world' of clinical experience over and above the 'proof' provided by systematic reviews and statistical evidence from clinical trials. The connections between evidence in peer-reviewed clinical journals and clinical practice have long been described as 'loose'[210] and this persists even in the present context of 'evidence-based medicine'.[211] Even if research-based scientific knowledge is taken up, it is interpreted and often reframed in clinical practice where power dynamics and political agendas between professional groups hold sway.[64,212] So, even when the scientific evidence is clear (and often it is not; rather there are competing bodies of evidence), disputes about efficacy may persist.[212] These complexities are inevitable because evaluation of technologies occurs mostly in practice and, therefore, evidence on clinical efficacy and utility only emerges over time.[19] Clinicians are often more convinced by the reported experiences of their colleagues than by forms of scientific evidence.[48,167] Fitzgerald *et al.*[212] outline four contingencies that influence the decisions of clinicians when deciding whether or not to use an innovation: evidence of adverse outcomes without the innovation; financial incentives for use or, at least, a neutral position on costs; evidence that other professionals use; and patient compliance and favourable reactions. However, 'use' cannot immediately be taken as clear evidence for 'usefulness', as some technologies are rapidly taken into practice but then later prove to be less than efficacious.[213,214] Another pertinent evaluation issue is that there may not be a lack of evidence per se, but hard-pressed staff in NHS organisations often do not have the time or skills to identify and evaluate it.[20] Indeed, it is argued that the explosion of medical knowledge greatly exceeds clinicians' capacities to understand, assimilate and translate into their practice.[211] Expectations over what an innovation can deliver vary according to how close the professionals concerned are to processes of knowledge production.[215]

Our case studies indicate that when the clinical utility and efficacy of innovations is still in question, academic clinicians in tertiary care are best positioned to evaluate the innovation concerned as they are most closely involved in knowledge production. As argued above, their expectations over what the innovation can deliver are likely to be more realistic. IPT is a mature technology. Although there were still some issues being raised over efficacy, at the NTAC implementation sites in particular, doubts over efficacy were muted. Indeed, for IPT the main focus was on increasing uptake. In contrast, for UFRI, debates over clinical efficacy and utility were central to both adoption and implementation. In particular, three questions were not fully resolved: *where* the technology should be situated (in tertiary, secondary or primary care, or all three); *how* the technology should be used; and *what* should be the target clinical conditions. Some consensus between the consultant ophthalmologists on the how and what issues was emerging, however, from the four tertiary sites. Academic clinicians in tertiary care were highly instrumental in leading the

**TABLE 6** Technology characteristics

| Characteristic | UFRI | IPT | BLNA |
|---|---|---|---|
| Technology role | Diagnostic | Support/treatment | Diagnostic |
| Life cycle | New/early | Old/late | Early/mid |
| NICE guidance | No | Yes | Yes |
| Early intervention or preventative role | Both | Preventative | Early intervention |
| Patient benefit | Early diagnosis and intervention in disease process; better diagnosis of peripheral conditions | Disease control and quality of life | Only one rather than two operations |

adoption and implementation of BLNA. Their collaboration was sought by NTAC in gathering evidence of cost savings that adoption of BLNA would generate, and findings from a study conducted by them were subsequently published in a peer-reviewed journal.[216]

However, Stevens *et al.*[217] point out that 'What is important is that any system for identifying and evaluating new technologies is linked to the system for knowledge dissemination and implementation. It must not stand in splendid isolation'. The UFRI and BLNA case studies indicate that the evaluation of these technologies is tending to stand in splendid isolation. The knowledge generated through use of these technologies within the sites concerned is underexploited because there is no link into any formal system for dissemination. The increasing development of joint higher education and health service collaborations, for example AHSCs, CLAHRCs and, most recently, the new AHSNs, should be a means to rectify this, although there is only limited evaluation of their roles to date.[218,219] However, recent evidence does support the concepts on which CLAHRCs and AHSNs are based. For example, across 12 case studies, Kyratsis *et al.*[220] found that local, practice-based, peer-mediated networks were seen as important for knowledge diffusion on technology implementation; in contrast, the centralised dissemination of evidence had only a minimal to moderate impact.

This theme of senior academic specialist clinicians driving and enabling technology implementation was echoed in both the UFRI and BLNA case studies. For UFRI, a few consultant ophthalmologists working in specialist centres (e.g. ophthalmic oncology) were working with Eyemap both for research and in the clinic. The issue for wider implementation was that their developing skills and knowledge with the technology remained trapped within their units. There were no formal channels for this expertise to be more widely shared. There was not even an informal network of these tertiary experts. Indeed, one of the consultant ophthalmologists expressed some concern that we might spread his research results to the others, and thus reducing their publishing impact. In the case of BLNA, apart from the role of academic clinicians noted above, clinical champions were identified as essential to success; being able to demonstrate their involvement was a condition for trusts being accepted into the NTAC project. NHS improvement networks (e.g. QIPP, cancer network) were singled out as important dissemination routes. The value of more informal professional networks was noted by our interviewees (e.g. pathology, procurement) for sharing knowledge of techniques and collaborating on equipment purchasing, but clinical networks did not play a significant role.

In the IPT case study, patients were significant in enabling the further implementation of the technology through their demand for the service; indeed, a patient support group (INPUT) was established to advocate for access to insulin pumps in the NHS. Our data illustrate that in some cases it was the push from patients and carers that mobilised NHS provider organisations to address the issue of IPT and develop the skills, knowledge and infrastructure to develop a pump service. Although patient pressure was not an enabler for UFRI, clinicians' desire in specialist oncology to use the Eyemap images to better communicate with

patients was a driver for implementation. Problems in patient communication are very common in medical practice, adversely affecting patient management and clinical outcomes.[221] Failed communication is the most common cause of litigation.[222] Patients appreciate honest information about the costs and benefits of treatment.[223] The Eyemap images enabled the consultant in specialist oncology to give patients realistic information about treatment outcomes which he thought avoided possible litigation.

In the case of BLNA, patient advocacy was mobilised through a breast cancer charity. NICE guidelines for the care of early and locally advanced breast cancer were included in the evidence base assembled by NTAC. The NICE guidance for BLNA is non-specific in that it only advocates minimal surgery. NTAC interprets the adoption of BLNA as compatible with this (see www.ntac.nhs.uk/HowToWhyToGuides/BreastLymphNodeAssay/Breast-Lymph-Node-Assay-Evidence-Base.aspx).

In the case of IPT, in particular, the NICE technology appraisal of IPT clearly acted as an enabling factor as it provided clinicians and trusts that were keen to implement the technology with a nationally recognised (and mandated) source of evidence that they could use to support their case, for example when negotiating with commissioners. Despite the fact that NICE technology appraisal guidance is expected to be implemented in practice/service delivery within a given time frame, the organisations we studied were not meeting the expected levels of pump provision for adults and children when they started working with NTAC. However, their willingness to develop the service (as evidenced by the fact that they applied to be an NTAC implementation site), coupled with the endorsed NICE evidence and the project management support provided by NTAC, created a set of enabling factors that facilitated the implementation of the technology in practice.

A classification of the case study technologies with regard to the enabling factors for adoption and implementation that we found is given in *Table 7*.

In a systematic review, Robert *et al.*[76] found that, first, professionalism and, second, power and politics impede the adoption of non-pharmaceutical technologies in health care.

Over the course of successive UK governments, policy decisions aimed at providing treatment for people with life-threatening conditions have resulted in acute hospital care assuming increasing prominence in the overall health economy.[224] Since the inception of the NHS the power of clinicians in tertiary and secondary care has greatly exceeded that of primary care, leading to a profound division between the two.[61,62] This division also occurs in health-care systems in other countries.[225] Accordingly, the ability to command and direct resources lies for the most part with tertiary and secondary care.[58,62] This is unfortunate as it is becoming clear that further increases in the cost-effectiveness of health care can only be delivered if more

**TABLE 7** Enabling factors for adoption and implementation

| Factor | UFRI | IPT | BLNA |
|---|---|---|---|
| Push for adoption | Producer | Patient | Clinicians |
| Clear location | No | Yes | Yes |
| Clear target conditions | No | Yes | Yes |
| Clarity on how to use the technology | No | Yes | Yes |
| NICE guidance | No | Yes | Yes |
| Clinical evidence base | Disputed | Largely accepted | Accepted |
| Clinical utility | Unresolved | Utility seen as being for the patient | High |
| Whole service benefit | Potentially high | High if it prevents disease progression | High |
| Tariff flexibilities | Not applicable | No | One pass-through tariff |

patient care, particularly for those with non-life-threatening chronic conditions, is undertaken in primary care.[224] Collaboration across tertiary, secondary and primary care is crucial for the successful adoption and implementation of UFRI. In this study, this collaboration was patchy at best. In general, it was not in evidence. Power, status differentials and politics are barriers to more collaboration between primary and secondary care. The most powerful differentiation in professional jurisdictions is between routine and non-routine work: technology can alter the differentiation between routine and non-routine, hence technology can reshape professional work.[126]

This potential reshaping was evident for Eyeco. Currently, HSOs can only detect eye pathologies, they cannot diagnose them. Detection is more in the nature of routine work than diagnosis. The greater education of optometrists (and GPs) in diagnosis would erode the power and status differentials between community-based optometrists and secondary care-based ophthalmologists. The current power and status differentials between primary and secondary–tertiary care created particular difficulties for UFRI and the realisation of the diagnostic potential of Eyemap.

Khandhadia *et al.*[174] comment that the development of Eyemap has created the possibility for community-based retinal assessment. Trials of community-based assessment (as compared with assessment in secondary care) have been shown to increase patient satisfaction, reduce numbers of patients with booked appointments who do not attend the clinic and save resources.[184] Efficacious assessment in community care could also aid in the earlier detection of eye pathologies. The tertiary specialist in ocular oncology who participated in our study commented on this with respect to Eyemap. Use of Eyemap in the community is supported by research studies. For example, Mayers[173] states that the Eyeco technology 'aids in the early detection of a variety of eye conditions including diabetic retinopathy, various forms of macular degeneration, posterior vitreous detachment, retinal holes and tears, hypertension, some types of leukaemia, and retinal detachment'. Education and knowledge dissemination from tertiary–secondary care are necessary for the successful deployment of Eyemap in primary/community care, however. The backdrop for the increased use of this diagnostic technology in primary/community care would be government policy for greater integration between primary and secondary care (see The King's Fund[224] for the issues associated with such integration). Greater integration, involving cross-boundary working, would enable the transfer of some work from secondary to primary/community care. For example, Field[226] comments:

> *For the NHS to survive and prosper and develop, it needs to work very differently and shift care from the hospital to the community. For that to work, we have to build capacity in primary care and that means we need to innovate, not just by using technology but by working differently.*

However, currently, as the UFRI case study demonstrates, power and professional politics at the primary–secondary care interface can be significant barriers to shifting care from the hospital to the community.

In the BLNA case study, political issues surfaced most clearly in the relationship between providers (the trusts) and commissioners (PCTs) of services, which, for provider business managers, were defined by PCT unwillingness to share the financial risks of adoption. In their view, this had a powerful, negative impact on the NHS's capacity to innovate. Instead of using their power as commissioners to drive innovation for patient benefit, with one exception, PCT negotiators were seen by trust business managers as being fixated on contractual details and risk avoidance. Hence, with that one exception, it was the providers who ended up taking on the role of drivers for BLNA adoption and taking on the risks. Delays in proceeding were an inevitable consequence. Whether or not PCT-led commissioning is the right model for all services, especially those of a more complex and specialised nature, has been questioned.[227] On the basis of international evidence, Ham[228] argues that the 'best performing [health care] systems are characterised by integration of commissioning and provision with alignment of incentives for clinicians'.

In relation to IPT, the most apparent barriers to implementation were observed in the NIS, where views about the strength or rigour of the evidence underpinning pump therapy were widely different among the

clinicians interviewed; some believed there was a strong case for providing IPT, whereas others questioned its safety and efficacy. In this latter group, objections were also raised in terms of the additional education and nurse support required to put patients on pumps, as this was seen to create inequity by taking resources away from non-pump users. Without external input, such as that provided by NTAC to the implementation sites, stakeholder discussions and meetings to explore differences of clinical opinion did not appear to have happened and the pump service was restricted to a clinical academic who was providing a limited service within an agreed budget.

The policy intent behind PbR is to augment activity and enable cost efficiency.[12,33,58] As yet, there is little systemic research on the impact of PbR on clinical technology adoption in the UK. Work (to date) indicates that PbR is slowing the rate of technology adoption. For example, FitzGibbon *et al.*[229] identify PbR as a significant barrier to the adoption of a point-of-care diagnostic technology, as the technology increased costs in the short term but this was not included in the tariff. This is clearly the case in relation to IPT, where initial investments to establish a pump service include both staff (specialist pump nurses) and resources (e.g. educational provision for staff and patients). This disincentive to adopt new technologies has been recognised for some time. In the USA, for example, Kane and Manoukian[230] showed that DRG payments impacted negatively on clinical technology adoption as the reimbursement did not generally cover the cost of the technology. They used the example of cochlear implantation, arguing that many years after FDA approval, DRG payment was still well below the average cost of the implant; in consequence, many hospitals rationed the device and, eventually, the manufacturers discontinued production. Policy guidance, from the UK Department of Health, allows for pass-through payments (to cover additional costs) to be made for new technologies for a period of 2 years if agreed in advance with the PCT.[231] Pass-through payments are made over and above the relevant tariff reimbursement.[33] In this study, however, few clinicians or managers seemed aware of this possibility (but for one exception see the BLNA case, in *Chapter 7*).

As noted above, the policy intent behind PbR is to augment activity and reduce waiting times.[12] However, it could also have the perverse outcome of encouraging trusts to maintain (or increase) inappropriate activity, particularly when, if activity decreases substantially, the consequence may be a financial deficit.[232] The possibility of loss of income from reduced referrals may have been a factor in the lack of enthusiasm for UFRI in secondary care. As noted earlier, meeting notes that we obtained indicated that at the site that eventually withdrew there was, initially, a declared intent to reduce inappropriate referrals from primary care and, therefore, focus clinicians' time on patients who genuinely needed to see a consultant in secondary care. However, concerns about loss of income to the trust were raised. In consequence, for UFRI, the professional power and politics issues that impeded the shifting of care from secondary to community settings (discussed above) may have been further hampered by the possibility of loss of income to secondary care.

In the case of BLNA one of the implementation sites had succeeded in negotiating a pass-through payment. There was, however, no clear process for the trust to follow. The assistant director of commissioning at the trust had contacted the SHA who, in turn, contacted the Department of Health. As a result of these contacts a pass-through payment had been forthcoming. At the other implementation sites, negotiations over how the financial impacts of BLNA would be resolved had not gone so smoothly and were seemingly contingent on the quality of the working relationship between the trust and PCT. Under PbR, providers are paid by commissioners at a fixed tariff according to the volume of activity,[233] hence a change to a care pathway that reduces activity (e.g. reduced bed-days) by the provider will lead to it losing financially, whereas the commissioner will gain. In principle, as it would now have spare resources it could deploy elsewhere, the provider could make up this loss by increasing volume in another service. However, as service volumes are set out in contracts, increases in other services would, themselves, have to be renegotiated. A trust director of strategy and planning observed that the PCT was suspicious that if second operations were prevented the trust would use these 'released' theatre sessions to do more work that would, in turn, mean that they overperformed on the contract with the PCT.

A classification of the case study technologies with regard to the barriers to implementation that we found is given in *Table 8*.

## Are processes for adoption generic or do the different types of technology require their own processes?

In this study we found certain generic issues, but some problems were specific to the technologies concerned. In terms of generic factors, the following are relevant: negotiating and implementing changes to the patient pathway; identifying training needs and, often, finding the resources to fund these; changing work practices; locating the resources to fund the purchase and use of the technology concerned, usually in the context of a decrease in patient throughput during the early stages of implementation and consequent loss of income under PbR; and, lastly, summoning the motivation, energy and commitment to overcome these barriers in the context of little time to devote to implementation while coping with ongoing clinical work. These generic factors demonstrate that clinical technologies are 'disruptive' in two senses. First, they have the potential to bring about step change improvements in patient care through disrupting traditional and sometimes out-of-date ways of working but, second, because they are disruptive to work practices they can elicit resistance. Theories of disruptive innovations in health care have been proposed, arguing that innovations are disruptive in health because they do not translate easily into 'value-added' business models.[234,235] *Innovation, Health and Wealth: Accelerating Adoption and Diffusion in the NHS*[1] suggests that *ease* of implementation influences the *rate* of implementation, so very disruptive technologies may take much longer to implement.

Current government policy as expressed in *Innovation, Health and Wealth: Accelerating Adoption and Diffusion in the NHS*[1] refers to '… game-changing innovations that change patient pathways and traditional delivery systems and … strip(s) out the processes that no longer add value'. This rhetoric neglects the issue that technologies have to be adopted and implemented by NHS clinicians (and managers) in the face of all the generic barriers identified above. Another rallying call is: 'We need to make innovation everybody's job from the top to the bottom of the NHS'.[1] At the moment, innovation is in nobody's job description: this is a generic barrier. In the case of new clinical technologies, the responsibility to adopt and implement is *assumed* by intrinsically motivated technology champions, usually clinicians but sometimes managers. Indeed, if technology implementation was 'everybody's job', it would be no one's responsibility as specific decision-making rights have to be delegated (or assumed) for technology adoption and implementation to progress (cf. Brunsson;[236] Ahrne and Brunsson[237]).

Our findings indicate that the NTAC approach to technology adoption and implementation was effective at addressing generic issues around changes to the patient pathway, training needs, rethinking work practices, harnessing energy and commitment for implementation and, to some extent, funding the

**TABLE 8** Barriers to implementation

| Factor | UFRI | IPT | BLNA |
|---|---|---|---|
| Involves complex new multiprofessional complex working practices | Yes | No | Yes |
| Capital cost | High | Low | High |
| Negative effect on trust income | Yes | No | Yes |
| Tariff rigidities | Not applicable | Only capital and consumables funded, not infrastructure | No local tariff agreed |
| Necessitates close working across PCT–trust interface | High | Low | Medium |

purchase and use of the technology concerned. To overcome these generic issues, NTAC employed the processes of project management and stakeholder engagement. As discussed earlier, NTAC established from the beginning that their work at the trusts was an implementation project rather than a trial. This did appear to ensure commitment and focus energies on a timetable with an end date and, for the MSs, the production of a HTWT guide. Also in relation to the issue that technology adoption and implementation is in nobody's job description, the project implementation manager role supplied a person around whom energies for implementation could coalesce. In a similar manner to a management consultant, this person was an 'objective' outsider removed from the trust's internal power and politics agenda and so, possibly, was more able to press ahead with implementation. Attention to stakeholder engagement ensured that all relevant parties were 'at the table'; apparently without NTAC's input, commissioners had been neglected, resulting in problems with funding. NTAC introduced a structured implementation schedule including meetings, presentations and awaydays, the formality of these processes imposed a dynamic that gave implementation an additional impetus alongside the day-to-day clinical use of the technology concerned. Participants also had the opportunity to share experiences, compare practices and learn from one another.

For IPT, we found that, in the two implementation sites studied, the processes underlying project management, stakeholder engagement and structured implementation schedules were largely sufficient to overcome the more generic barriers the sites were dealing with. In both sites, there was a general receptivity to IPT as a technology and a willingness to increase its use. However, the main barriers were around how to get started and how to manage the process of implementation, including the various stakeholders that needed to be involved. This does, however, raise the question of whether or not the more generic support provided by NTAC would work in organisations that would not fit the criteria of 'early adopters',[27] such as the NIS where there was a greater contestation of the evidence and less receptiveness to the technology of IPT.

As indicated earlier, the NTAC project implementation for UFRI failed as all the interested trusts withdrew. Based on our findings, however, we judge that even if the trusts had remained interested the project would have been unlikely to succeed. The technology was too disruptive. The processes of project management, stakeholder engagement and structured scheduling (to address generic issues) would have been unlikely to solve the complex issues of where the technology is best situated (primary, secondary and tertiary care or all three), how the technology is best used and what target conditions the technology is best used for. The emerging scientific evidence in journals and the ongoing research in tertiary care (including use in the clinic) is resolving the 'how' and 'what' questions, but the 'where' question (apart from in tertiary care itself) is not being addressed. As argued earlier, to reap its potential UFRI requires a close working relationship between partners in primary and secondary care and willingness on the part of tertiary (or secondary) care to educate primary care. Education is required for the 'how' and 'what' issues; in addition, our research found that there is a long learning curve in interpreting the digital images. Without some integration between primary and secondary care, education on this scale seems unlikely to happen, given that there are, currently, no financial incentives for ophthalmologists in secondary and tertiary care to engage. Indeed, if the use of the technology in primary care reduced the number of referrals to secondary care (which seems likely over time), there is a financial disincentive for the trusts, although there should be savings for the health economy as a whole.

Breast lymph node assay adoption called for a number of significant changes in working practices of surgical and pathology teams. First, it made the management of theatre lists more complex as provision had to be made for additional surgical time, but which patients would need it could not be predicted with complete confidence in advance. Second, it demanded much closer co-ordination between surgical teams and pathologists, as test results had to be available within a very short time period. We saw different ways of achieving this at each trust, some of which were acknowledged to introduce some potential risk to the reliability of testing procedures. In general, the implementation of these changes was contingent on local factors, making it difficult, if not impossible, to propose a 'standard' for implementation that could be straightforwardly applied at any trust.

## What role does the wider commissioning process play?

Against a background of perceived poor commissioning performance, a programme for 'world class commissioning' began in the English NHS in 2007 with the intention of developing and strengthening PCT commissioning of health services.[238] The advent of the Coalition government in 2010 led to the abolition of PCTs and their replacement by the NHS Commissioning Board and CCGs.[239] Despite these structural changes, commissioning continues to face the same challenges. Foremost among these is the ability of commissioners to negotiate on a 'level playing field' with the providers of care,[240] which, in turn, is dependent on equal access to appropriate information about the cost and quality of health-care services. Moreover, even in a more marker-orientated regime, there are indications that a cultural climate that enables relational (encompassing trust, common values and networks) rather than adversarial (or legalistic) commissioning is more effective.[241] Effective 'commissioning' is more than purchasing, purchasers merely buy what is already available or reimburse providers according to their use of the services providers offer. In contrast, commissioning should involve 'a proactive strategic role in planning, devising and implementing the range of services required'.[242]

Commissioning, therefore, should be a driver for technology adoption and implementation, particularly where there are potential savings for the health economy as a whole. Equally, commissioning may involve decommissioning where an activity no longer adds value or has been shown to be outmoded.[1] To better guide the implementation of clinical technologies, *Innovation, Health and Wealth: Accelerating Adoption and Diffusion in the NHS*[1] is introducing a National Institute for Health and Care Excellence Implementation Collaborative (NIC) comprising NICE, the NHS Commissioning Board, the chief pharmaceutical officer, the main industry bodies, the NHS Confederation, the Clinical Commissioning Coalition and the Royal Colleges.

The findings from our case studies indicate that a body such as NIC will be valuable once a technology has been evaluated in clinical practice. The learning curve on clinical efficacy and utility for technologies is such that the NIC will be unable to drive technology adoption until providers have evidence of added value. So we think that the NIC will be important in ensuring diffusion once clinical efficacy and utility are evaluated and the technology is domesticated, i.e. it fits into practices and routines (see, for example, Berker *et al.*[185]).

Overall, our evidence on the role of commissioning in relation to UFRI, IPT and BLNA indicates that commissioners play a purchasing, rather than the broader strategic 'commissioning', role in relation to technology adoption and implementation. The lead commissioner for the WIS for UFRI indicated that he had identified ophthalmology (along with orthopaedics and ear, nose and throat) as the biggest referring specialties. He went on to say that he knew that there were 'lots of' ophthalmic referrals that could be managed in primary care or by opticians. Yet, when asked if commissioning should drive technology adoption, particularly where the technology concerned could enable the management of more referrals in primary care, he responded that commissioners do not purchase technology, they buy patient outcomes. This approach clearly locates the responsibility for technology adoption and implementation with the trusts. He added that commissioners are not 'against technology if it improves efficiencies'. Such a line hardly points to a strategic role for commissioning in technology adoption and implementation. It should be pointed out, however, that without a NICE technology appraisal, commissioners are reliant on evaluations undertaken at the trusts for their evidence on clinical efficacy and utility. None of our respondents in the UFRI case study mentioned any current commissioning plans to shift some ophthalmic care out of the trusts into community settings. The only example of such a possibility was given by an optometrist where optometrists and a GP had built up a plan to open a community ophthalmic unit, but the move was 'stamped upon' by one of the consultant ophthalmologists at the local trust. The business and development manager at the withdrawn UFRI implementation site had initially contacted the PCT and persuaded them to fund the technology, but when the trust decided not to go ahead there is no evidence that the commissioners had responded with any objections. However, as pointed out earlier, we were unable to obtain the minutes of the meetings between the trust and the PCT over this withdrawal,

as both sides stated that they had lost them. Subsequently, we put in a Freedom of Information request but still no documents were forthcoming.

Similar observations of commissioners' roles were made by trust business managers in the BLNA case study in the sense that the acute trusts approached the PCT to tell them they should be commissioning the BLNA, although the trusts were aware that policy expressed the view that commissioners should drive innovations.

## What is the role of the technology producer in supporting adoption in health-care organisations?

Faulkner[243] points out that the medical device industry and the health-care state are closely interwoven. Yet, Wanless[2] identified the NHS as a 'slow and late adopter' of medical technologies and predicted that this would, increasingly, become a performance issue. Sir Bruce Keogh, the current NHS Medical Director, commented in 2012, 'Even with hard evidence of superior efficacy it generally takes around 15 years, in any health-care system, for widespread adoption of a new intervention'.[244] The role of the producer in supporting adoption is, therefore, potentially important in facilitating the use of efficacious clinical technologies which can leverage NHS performance. In the UK, there are around 2000 companies that produce medical devices; about 85% of these are small firms, so the industry is unlike pharmaceuticals (where companies are large and globalised).[243] As most UK medical devices companies are SMEs, their future in the UK market is rather precarious until their products are fairly widely adopted within the NHS, as private health care is used by <8% of the UK population. This gives clinical technology producers a clear incentive to engage in strategies to increase the uptake of their devices. Yet, through the present 'bottom-up' (i.e. at trust level) implementation process this is not an easy or straightforward task. As there are around 250 trusts in England alone, at the most basic level this could mean 250 contracts to be negotiated and established. One of the former project implementation managers at NTAC plans to start a consultancy advising UK technology producers on how to navigate the complexities of the UK NHS when they are seeking to find a market for their new devices.

Producers have strategies to increase the uptake of their products. Currently, it is common practice for technology producers to provide demonstrations of their clinical technologies at NHS trusts in an attempt to sell the 'competence' of their innovations. They also sometimes offer free trials to allow potential users to evaluate and test the capability of clinical technologies. Demonstrations of technology are organised events where the capabilities and features of technology are revealed to potential adopters and users.[245] Such presentations can more resemble 'infomercials'[48] than be driven by evidence-based reasoning. Nevertheless, they represent a defining moment in the adoption pathway, designed to provide evidence to various stakeholders about the efficacy of technologies and systems, either under development or ready for use.[246] However, demonstrations are not simply about evaluating technologies (i.e. providing evidence for or against adoption). Nor do they straightforwardly evaluate suppliers (i.e. assessing the 'status' of producer and suppliers' 'track record'). They play a crucial role in the 'negotiability' of uncertainty and risk of adoption. Indeed, as 'infomercials',[48] much of the promise of new clinical technologies depends on masking such uncertainty and mobilising a range of claims and expectations about the capabilities and future trajectory of innovation. In this context, it is suggested that expectations mobilised in the representation of technological innovation do not simply describe these future technologies but also help bring them into being.[245,247,248]

Clinical technology adoption and implementation both happen in the context of uncertainty. As pointed out above, evidence about the clinical efficacy and utility of technologies is negotiated and evaluated over time as medical devices are used in practice. *Innovation, Health and Wealth: Accelerating Adoption and Diffusion in the NHS*[1] notes that the UK is strong in biosciences (see also Faulkner,[243] who states the UK is a net exporter of medical devices) and recommends 'partnership' with industry producers, emphasising that the NHS should adopt and implement technologies that improve productivity and add value but not

cost. To this end, the following is suggested to 'work with industry to develop a better "value proposition" for the NHS, relying less on upfront capital or revenue investment, and more on taking income from downstream revenue savings'.[1] Recognising the problems producers have in terms of accessing individual NHS trusts (see above), the government has instituted AHSNs to help with access. AHSNs would function as 'lead customers' working jointly with industry to scope barriers and develop solutions to problems with technology adoption and implementation.[1] Better metrics on innovation uptake is also recommended, as is making the uptake of 'high impact' innovations mandatory.[1] Overall, the commendation is that AHSNs would work with industry on the 'evaluation, commercialisation and rapid adoption of health technologies … [whilst] creating wealth for UK PLC'.[40]

The evidence from the three case studies indicates that the industry producer was actively involved only in negotiating the uptake of the technology for UFRI. Unlike IPT and BLNA, the UFRI technology had not undergone a NICE appraisal – resulting in a guideline – so this 'push' factor was lacking. As mentioned earlier, the clinical efficacy and utility of this technology was disputed. For example, the possibility of using non-dilated digital Eyemap images rather dilated clinical examination was debated. In consequence, Eyeco had grant-funded several clinical trials. One of these, the 'Joslin Trial' in the USA, recently reported:

> *Nonmydriatic [non-dilated] ultra wide field images compare favorably with … dilated fundus examination [clinical examination of the retina] in determining DR and DME [diabetic retinopathy and diabetic macular edema – both eye conditions associated with diabetes] severity; however, they are acquired more rapidly. If confirmed in broader diabetic populations, nonmydriatic ultrawide field imaging may prove to be beneficial in DR evaluation in research and clinical settings.*[183]

The tertiary specialists who participated in our research were aware of this study but the relevance of non-dilated vis-à-vis dilated eye examination is more relevant in secondary and primary care, as dilation is the norm in tertiary care. For the industry producer of Eyemap this is the type of research finding for which access to an AHSN, to enable rapid dissemination in secondary and primary care, would be particularly valuable. Eyeco had also funded a US ophthalmologist who was skilled both in the use of UFRI and in the interpretation of Eyemap images to advise any clinicians who had adopted UFRI, but who were on a learning curve in terms of diagnosis from the images. This person gave advice over e-mail after receiving the digital images. Again, within the context of partnership between the NHS and the industry producer, the expertise of this funded US ophthalmologist could be mobilised more widely. As mentioned above, *Innovation, Health and Wealth: Accelerating Adoption and Diffusion in the NHS*[1] envisages industry producers taking revenues 'downstream' after productivity gains from the technology have become apparent. The problems with this, from the point of view of the producers (SMEs in the main), are that cost savings are difficult to estimate; such savings may accrue only after many years of using the technology (e.g. for diagnostic technologies, such as UFRI, earlier detection and prevention of disease will reduce health-care costs over the longer term); and, financially, many SMEs are dependent on positive cash flows to maintain the viability of their businesses.

There was no producer push in the BLNA case study, their role was notable mainly for Checklog withdrawing their product from the market just as the project was getting under way. This caused some disquiet initially. However, in the end, the impact was short-lived and negligible. First, there had been no consensus among the biomedical scientists as to which of the two assays was best. Factors that had to be considered included material costs (reagents), precision of the assay (false-positive and -negative rates), complexity of the process, staffing and availability of training, and these weighed up differently in the individual trusts. Two had opted for the Checklog assay and two for Orglog. Second, the impact on the former by the Checklog withdrawal was resolved when Checklog consented to granting them a royalty-free licence to develop in-house a similar assay and to make it available to other trusts. The only problem was that validating the in-house assay would take additional time and so created a delay before it could be used by other trusts.

In the case of IPT, there were a number of different producers in the market for trusts to choose from and procurement of pumps was one of the issues addressed within the NTAC implementation project. Pump companies often provided practical help to trusts, for example through the company-employed pump nurses providing educational support to staff in the initial stages of setting up a pump service.

## How does the presence of and intervention by NHS Technology Adoption Centre impact on the process of adoption within the institution?

We have already commented at some length on the role of NTAC in *Chapter 4*. Above we identify their work practices as project management, stakeholder engagement and structured scheduling. It is worth emphasising that NTAC is not focused on 'upstream' technological innovation; it works 'downstream' with trusts that have adopted a technology but are experiencing problems and want support to implement that technology. We argued that, conceptually, the NTAC approach can be understood through Callon's 'four stages of translation', where the first stage is 'problematization', where an objective (technology implementation) is seen as shared across different sets of actors (clinicians, managers and commissioners), but one set of actors (in this case NTAC) position themselves as key in terms of accomplishing this objective. The second stage is 'interessement', where the key actors propose roles for the other sets of actors and gain their commitment to particular courses of action with respect to the objectives. Callon's third stage is 'enrolment', where the proposed roles and courses of action are operationalised and consolidated. Finally, the fourth is the stage of 'mobilization of allies' where further actors are drawn into the established networks, and communication among this enlarged group is enabled through 'immutable mobiles'. Analysis of how NTAC was perceived in the different IPT and BLNA sites does tend to support these concepts. NTAC was regarded as a 'catalyst' for action. As an 'outsider', it was viewed as being able to 'force' different players to come to the table – where, previously, key actors had sometimes refused to participate in discussions on technology implementation. Some participants acknowledged that their own approach to implementation had been 'ad hoc'; in contrast, NTAC brought a co-ordinated 'road map'. In addition, some trusts had not thought about involving their commissioners, whereas NTAC identified them as crucial, albeit that some BLNA sites did criticise NTAC for not involving commissioners. In terms of the 'mobilization of allies', respondents commented that once their implementation project was under way they were able to link into networks with staff at other trusts (i.e. other NTAC implementation or MSs). This networking enabled constructive exchanges on comparing practices and solutions to common problems. There were some comments, however, that the NTAC work was 'on paper' and the 'real work' began after their departure. Nevertheless, there was considerable positive feedback from the sites on NTAC's presence at the trusts and the interventions they made to improve the implementation process.

On the other hand, there were areas where the NTAC approach could be critiqued. First, the success of the implementation projects at the sites was very dependent on the skills and enthusiasm of the individual project manager. There did not appear to be much managerial oversight of the work of these implementation managers. The trust that withdrew from the UFRI project seemed to make this decision on the basis of one particular meeting where the producer demonstrated the technology. There did not appear to have been much work to engage stakeholders in meetings before this demonstration to clarify expectations and work through difficulties. As outlined in *Chapter 5*, the complexities around adoption and implementation were considerable and the NTAC approach of working within secondary care (rather than across organisational boundaries between primary, secondary and tertiary care) was not really suited to this technology, so the implementation project may have failed anyway, but the way that the project was managed at the start did not seem optimal.

Second, expectations that the HTWT guides could support trusts through technology implementation without NTAC's active intervention 'on the ground' look overly optimistic. In ANT terms the HTWT guide was conceived by NTAC as an 'immutable mobile' in the sense that the guide could 'move around' from trust to trust and also could achieve 'universality' (i.e. immutability) because it embedded the learning

from several implementation sites (cf. Law and Singleton[249]). The responses of trusts who had used the guides, however, indicate that they felt that the guides did not have universal applicability. Respondents expressed the views that the guide did not 'mesh' with their particular circumstances, was only a 'reminder' of what they already knew and did not give them the answers to the specific problems they were experiencing.

## Does the involvement of NHS Technology Adoption Centre have an impact on the sustainability of adoption? Does the technology remain embedded after NHS Technology Adoption Centre withdraws? Can the issues and processes that cause it to continue or fail to remain embedded be identified?

As this research was limited to a 3-year time scale and the IPT and BLNA case studies were undertaken after the research on UFRI, our findings cannot be definitive on the sustainability of IPT and BLNA at the sites. We did not observe any indications that IPT or BLNA would not remain embedded at the sites. The issues with regard to the sustainability of the two technologies were rather different, however. For IPT, the trusts were attempting to increase the proportion of patients on pumps who met the NICE criteria, so sustainability would equate to continuing to increase uptake until the NICE guideline was met or, indeed, overtaken. For BLNA, all women undergoing breast surgery for cancer were offered the assay, so sustainability could not be measured by increasing proportions of women avoiding the need for two operations.

Lettieri and Masella[55] drew on 13 studies of technology adoption and implementation to define five dimensions that determine the sustainability of any technology (see also *Chapter 2, Variable local decision-making processes*):

- *financial* sustainability (e.g. the ability to sustain cash needs)
- *organisational* sustainability (e.g. the inertia or resistance to change)
- *technological* sustainability (e.g. the evolution of technology)
- *resource* sustainability (e.g. training needs)
- *context* sustainability (e.g. the demand of health services).

With regard to financial sustainability, none of the sites had negotiated a local tariff with the PCT (or PCTs) for either IPT or BLNA. At the IPT sites, on account of the NICE guideline, most participants reported that the PCT was willing to fund the equipment costs for the purchase of the pump and the consumables on an ongoing basis for patients who met the criteria. However, respondents were uncertain, once the NICE guideline of 15% of patients with type 1 diabetes was met, if the PCT would continue to meet the costs. For one of the sites, a specialist children's centre, this ad hoc negotiation with the PCTs was a concern as they had 17 PCTs to deal with. Given that the PCTs would fund IPT, none of the sites had submitted a business case to trust management. Most IPT sites argued that they needed a specialist pump nurse to meet the additional patient need for education and advice to use the pumps safely. The PCT would not fund these additional staff costs; the trust had to meet them. Therefore, in terms of financial sustainability, IPT is dependent on the continuing support of the PCT and, to a lesser extent, trust management. For BLNA, financial sustainability, at the level of the trusts, was less clear. NTAC estimated that if BLNA was implemented across the entire NHS, on the basis of ward costs alone, there would be savings of £4M per annum and the total savings would be around £5.1M (see www.ntac.nhs.uk). Nevertheless, under PbR, the trusts lose income as the introduction of the assay means that 25–30% of patients undergoing breast surgery for cancer will not need a second operation. One of the BLNA sites had negotiated a pass-through payment (a 'top-up' to the tariff) with the local PCT but at the other sites negotiations with the PCT were ongoing and unpredictable. Financial sustainability for BLNA was somewhat uncertain, despite the potential savings for the whole NHS economy.

Organisational sustainability seems strong for BLNA. The technology inspired enthusiasm and commitment from the clinicians; it was described as a 'no-brainer'. Also, once joint working between histopathologists, breast surgeons and theatre staff was instituted, the new patient pathway looked embedded. In contrast, the commitment to IPT looked more variable between different clinicians, with some demonstrating high motivation but others showing some resistance, even describing pumps as 'elitist' and a 'lifestyle' choice for patients. At one of the sites the continuing implementation of IPT had been delegated to the nursing staff.

As a mature technology, IPT had low technological uncertainty. There were several pump manufacturers so availability was assured. In contrast, as a newer technology there were some questions over the availability of BLNA. There were two different assays commercially available, but the manufacturer of the one generally deemed as superior had pulled out, citing financial reasons. Two of the BLNA implementation sites had the expertise to develop their own assay based on their knowledge of the withdrawn system (there were no intellectual property issues). However, the other sites did not have the expertise to do this and the second system was considered somewhat inferior. Hence, there were some unresolved questions over the technological sustainability of BLNA.

As training needs had been met at the BLNA and IPT sites, in this regard, resource sustainability was not a problem. However, the BLNA technology put pressure on human resources within pathology and introduced uncertainty into the management of theatre lists, and some sites argued that additional breast care nurses were needed to cope with the increased patient anxiety. In a similar manner, the resource sustainability of IPT depended on the infrastructure provided by a specialist pump nurse and access to educational resources for patients.

Insulin pump therapy and BLNA had associated NICE guidance, so context sustainability was, to some extent, assured. Context sustainability for IPT was further augmented by patient demand. Clinician enthusiasm and commitment provided additional context sustainability for BLNA.

NHS Technology Adoption Centre interventions focused mainly on organisational, resource and context sustainability. Although they tried to ensure financial sustainability, through involving the relevant PCTs in the implementation projects, our findings show that presence of NTAC was not always successful in ensuring formal arrangements for financial sustainability. Short-term solutions, for example the PCT funding the actual costs of IPT on a patient by patient basis, predominated. Technology sustainability was outside NTAC's control.

## What information can be gathered from the NHS Technology Adoption Centre project to assess the wider impact on how implementation is managed?

Our findings indicate that the NTAC approach is most suited to a technology like IPT, where the problems are generic ones around managing changes to the patient pathway, identifying and meeting training needs, negotiating new work practices, being a catalyst to generate energy and commitment for implementation and, to some extent, funding the purchase and use of the technology concerned. We judge that the resources that can be mobilised by a small organisation such as NTAC are insufficient to tackle a technology like UFRI, which, along with these generic issues, had a contested evidence base and necessitated large-scale intervention to span the boundaries of primary, secondary and tertiary care to overcome resistance generated by professional power and politics. Although the expertise of NTAC was clearly helpful for the BLNA project, their intervention seemed less necessary where there was clear clinical commitment and enthusiasm for implementation. We judge that technology implementation should be finessed dependent on the extent and nature of the barriers encountered, which, in turn, vary with the type of technology. The NTAC approach of working within secondary care on project management, stakeholder engagement and structured scheduling meets many needs but, on the basis of our experience

with three different technologies, is somewhat limited and inflexible for some clinical technologies. This reinforces the evidence from the literature, which strongly supports the view that there is not a 'one size fits all' approach to implementing evidence and innovation.[250]

## Meeting aims and objectives

We next discuss how far we were able to meet our aims and objectives. For clarity we set them out again as follows:

The aims of this research were:

- to identify the root causes of risk perceptions over technology adoption in the 'sponsoring' trusts
- to map out the network of actors required for successful technology adoption
- to understand the policy, organisational and cognitive barriers and resolve cross-boundary issues
- to assess the extent to which PbR is creating barriers to technology adoption and implementation.

Our specific objectives were:

- to produce recommendations on 'what needs to change' for successful technology adoption [such recommendations will seek to change any misguided perceptions of risk through communication and alleviate real risk (e.g. of income loss) through cross-boundary negotiations]
- if PbR funding mechanisms are too rigid, to make recommendations of how local flexibilities can be enhanced
- to identify any new boundary-spanning roles required to facilitate technology transfer along the adoption pathway
- to work closely with NTAC to ensure that this research dovetails with its agenda (the technologies we will investigate have been chosen in consultation with NTAC).

In terms of meeting our aims, technology adoption and implementation always involves changes to the patient pathway and existing work practices, necessitates training and usually involves new infrastructure. These changes result in risk and uncertainties; these have to be negotiated along the lines that we have outlined above. In local terms it was not necessary for us to map out the network of actors needed for technology adoption and implementation because NTAC had already accomplished this. However, these local trust-based networks need to be linked into wider top-down initiatives to ensure that technologies are adopted into the most optimal settings and diffusion takes place to all appropriate organisations. We have provided our understanding of the main policy, organisational and cognitive barriers in the above discussion. The major cross-boundary issue was the lack of integration between primary and secondary–tertiary care. This prevented secondary care providing the necessary education for primary care to adopt UFRI. This issue is intractable to the efforts of a small research team. We were, therefore, unable to resolve it. As discussed above, PbR is a major barrier to the adoption and implementation of new clinical technologies. However, as pointed out, the flexibilities provided by pass-through payments and local tariffs were not taken advantage of. As we discuss, lack of trust between providers and commissioners tended to prevent this. There is a potential role for trust managers in negotiating tariff flexibilities but, currently, few managers occupy these roles. We point to 'what needs to change' for successful technology adoption and implementation in our recommendations on best practice below. As mentioned above, new boundary-spanning roles between secondary–tertiary and primary care were necessary for the adoption of UFRI, but PbR prevented consultants from assuming these roles, as there is no payment for them under the tariff. We were able to collaborate with NTAC but, over the life of the research, policy changes restructured the way that NTAC works, rendering its input more directly tied into specific Department of Health initiatives. In consequence, NTAC's methodology shifted and it was less able to work 'on the ground' at the trusts. Our research with NTAC was, therefore, more retrospective than planned at the beginning of the research.

# Conclusions

Finally, we note the limitations of our study, outline possibilities for further research and consider if it is possible to define best practice for technology adoption.

## *The limitations and difficulties of the study*

This research was funded to explore the organisational and policy issues with regard to technology adoption and implementation. We found, however, that it was impossible to draw a clear distinction between organisational issues and ones of clinical efficacy and utility. For example, interorganisational power and politics had a significant impact on assessments of clinical efficacy and mediated what could be achieved on utility.

Our study has been shaped by its focus on NTAC as an intermediary organisation supporting the process of technology adoption in the NHS and by the specific technologies that NTAC was involved in supporting, which might have an impact on the generalisability of our study findings. In terms of the inter-relationships between adoption and implementation and diffusion, because the research incorporated a critique of NTAC, our work focused more on implementation than the decision to adopt or the processes to diffuse a technology. Our three technologies were chosen, in consultation with NTAC, from its portfolio. We decided that an in-depth analysis of three hard-to-implement technologies was likely to prove more informative than a superficial approach over many. However, given that we found that two of the technologies (UFRI and BLNA) threw up specific adoption and implementation problems, it remains to be seen if other technologies will also present unique challenges. Hence, we cannot claim to have covered all possible barriers and enablers. In terms of the generalisation of our findings, the operational issues (e.g. changes to patient pathways, training requirements and cost implications) applied to all three technologies are generalisable and echo the findings of previous studies.[19,44,49,52,251] In this respect, all three technologies were typical. However, other, more strategic, issues are clearly tied to specific technologies (e.g. education across tertiary, secondary and primary care for UFRI). Although case study research such as this can anticipate strategic issues arising, it cannot always predict the future. The dynamic nature of policy change and social processes make generalisation time-limited.

Our data collection was largely qualitative but we were able to produce some quantitative survey findings with regard to the uptake of IPT. This IPT survey was not specified in the proposal but we carried it out because an opportunity consequently presented itself. One of our advisory board members had a contact in a newly established IPT network organisation. As explained in *Chapter 3*, we were not able to conduct follow-ups to improve the response rate because we were reliant on the goodwill of the network manager to send out the survey.

## *Future avenues for research*

In the context of the current restructuring of the commissioning function around the NHS Commissioning Board and CCGs, research on the impact of these new bodies on technology adoption and implementation looks necessary. As discussed above, *Innovation, Health and Wealth: Accelerating Adoption and Diffusion in the NHS*[1] envisages a NIC to work with NICE and the NHS Commissioning Board (now NHS England) to extend NICE's technology advice and guidance. The NHS Institute has been abolished, with some of its functions being incorporated into NHS Improving Quality (NHS IQ) (part of NHS England). Among other things, NHS IQ will 'support … Academic Health Science Networks in delivering improvement goals to support transformation' and build transformational capability within CCGs and primary health-care providers, and for whole-system transformation.[252]

Our findings indicate that this looks a promising strategy as NICE guidance acted as an enabler for adoption and implementation. However, our evidence does not give confidence that commissioners are able or willing to drive technology adoption and implementation, despite the potential for NHS IQ to continue the work of the NHSI in this area. This future integration between NICE and the commissioning function has uncertain outcomes.

Such research could help the NHS to get commissioner-driven adoption and implementation right, thereby reducing inequalities in access to new technologies, increasing technology adoption in primary and community care and in health promotion and prevention, and making technology adoption more sensitive to patient needs.

We now turn to our final research question.

### *Is it possible to identify best practice(s) for ensuring technology adoption? Are there key roles for managers and other decision-makers (e.g. clinicians, board members, patients)?*

NHS Technology Adoption Centre is focused on implementation rather than adoption. Earlier we pointed out that there are several frameworks that usefully distinguish these. Frambach and Schillewaert[25] make a distinction between initiation, the adoption decision (which may be to reject) and implementation. Williams and Dickinson[26] see initiation as setting the adoption agenda, including a consideration of how the technology will be used in the organisation; they view implementation as being distinct from the routine use of the technology. Clearly, there also has to be an awareness of the technology for initiation to begin.

Our findings indicate that adoption is a decision that is made locally, i.e. by a clinician (or clinicians) or, less frequently, managers within secondary or tertiary care (or, more rarely, within primary care). These individuals are acting on their awareness of the particular technology and initiate consideration within their organisation. This approach has some advantages, as technologies, unlike pharmaceuticals, have a learning curve so require evaluation within a hospital or care setting. Leaving the adoption decision to individuals has disadvantages, however, because it is essentially a 'market' approach. There is no guarantee that the setting within which the individual works will be the right one for the particular technology. For example, a decision to implement UFRI in secondary care would be less than optimal as our findings show that the technology required evaluation in tertiary care before deployment in other care settings. In addition, this 'market', atomised approach does not work well when successful deployment requires education across the tertiary–secondary or secondary–primary divides. Again, UFRI was an example of this. Equally, this local 'bottom-up' approach to adoption and implementation does not ensure diffusion of the technology beyond the particular adoption site. The HTWT guides are intended to achieve diffusion but our evidence is that they do not work well.

Our findings point to clinicians, in particular consultants with academic posts, as the main instigators of technology adoption. In terms of ensuring implementation, the expertise of managers at the trust appears to be rather underutilised. For example, we found only one instance of a manager negotiating a pass-through payment (this was for BLNA). Although it was understandable that, under PbR, trusts will be reluctant to introduce any technology that reduces income, there was little evidence of managers making business cases on the basis of calculations of increased productivity in the longer term. Although we found one example of this with respect to UFRI, a business case had been successful when it was argued that UFRI increased patient throughput in the clinic. We found no evidence of commissioners actively driving technology adoption and implementation. For BLNA and UFRI, this situation was curious because both technologies had the potential to reduce costs for the whole health economy. Commissioners, like providers, appear to be focused on short-term budget savings at the expense of longer-term gains in productivity.

Ong *et al.*[45] present a typology of drivers for technology adoption: maximising profit, maximising competitive advantage (through technical superiority which enhances status and prestige, and thus attracts patients, clinicians and researchers) and maximising utility (to enhance the quality and quantity of provision). In terms of this typology we found a more or less exclusive focus on short-term profit maximisation. Maximising utility appeared to be a driver only when increasing the numbers of patients treated, resulting in increased income under PbR.

Patients were a significant pressure for increasing numbers on IPT once the trust had made the decision to adopt the technology. We found no evidence for the involvement of board members in technology adoption or implementation.

We identified both PbR and interorganisational power and politics as significant barriers to the adoption and implementation of clinical technologies. Given these contingencies, commissioning should be a driver, but our evidence indicates that commissioning will work best when used in a collaborative manner rather than through rigid contracting. Recent evidence does not bode well for this, however. Checkland *et al.*[253] noted that only 26% of the 118 CCGs in their sample had appointed a secondary care consultant to their governing body, even though it has been known for some time that this role is likely to be a requirement. Checkland *et al.*[253] reported that CCGs appeared resentful of this requirement and the general feeling was that the secondary care role would not add value to their work.

We conclude that the present atomised, bottom-up manner of technology initiation and adoption where trusts could choose to adopt any, all or none of the clinical technologies we investigated is undesirable, as clinically efficacious technologies should be equally available to all patients. Therefore, the present system should be mediated by some greater 'top-down' policy direction to ensure a good fit between the technology and the care setting, and encourage diffusion to other appropriate sites, so that patient benefit from technology is maximised. *Innovation, Health and Wealth: Accelerating Adoption and Diffusion in the NHS*[1] draws on evidence from the *Atlas of Variation in Healthcare Series*[254] with regard to technology adoption to acknowledge that more 'push' and direction from above is necessary to ensure that, where a technology can add value, its use is replicated across all appropriate settings. However, as noted above, local, practice-based, peer-mediated networks diffused best practice on clinical technologies better than centralised policy guidance so there seems to be good potential for AHSNs to link bottom-up adoption with top-down national policy processes; however, other linkages may also be necessary. Incentive money to cover the costs of early adopters should be considered and pass-through payments for new technologies should be much more readily available. Clinical 'czars' could be appointed for new clinical technologies to drive commitment, transfer knowledge across settings and monitor adoption, implementation and diffusion rates.

Overall, given the adoption–implementation–diffusion process for clinical technologies, our findings indicate that the NTAC approach works well on generic implementation problems, but more attention should be given to the specialised requirements of particular technologies. Moreover, successful adoption and diffusion call for greater 'top-down' direction and interventions to formalise and drive 'lateral' network processes.

# Acknowledgements

The research team would like to thank all the members of our advisory board and all the participants in the research for their time and commitment to the project. The staff of NTAC were very helpful over introductions to relevant stakeholders and offering feedback. Lesley Jordan (an advisory board member and leader at INPUT) assisted us greatly over the patient perspective. Thanks also to Andrew Webster for leading our main dissemination event.

Finally, thanks to Chris Wood for all his excellent administration.

## Contributions of authors

**Sue Llewellyn** (Professor, Healthcare Management) contributed to designing the study, data collection, data analysis and report writing.

**Rob Procter** (Professor, Technology Studies) contributed to designing the study, data collection, data analysis and report writing.

**Gill Harvey** (Reader, Healthcare Management) contributed to designing the study, data collection, data analysis and report writing.

**Gregory Maniatopoulos** (Research Associate, Technology Studies) contributed to data collection, data analysis and report writing.

**Alan Boyd** (Research Associate, Healthcare Management) contributed to data collection, data analysis and report writing.

# References


1. Department of Health. *Innovation, Health and Wealth: Accelerating Adoption and Diffusion in the NHS*. London: Department of Health; 2011.
2. Wanless D. *Securing our Future Health: Taking a Long-term View*. London: HM Treasury; 2002. p. 39.
3. Suggs LS. A 10-year retrospective of research in new technologies for health communication. *J Health Commun* 2006;**11**:61–74. http://dx.doi.org/10.1080/10810730500461083
4. Kennedy CM, Powell J, Payne TH, Ainsworth J, Boyd A, Buchan I. Active assistance technology for health-related behavior change: an interdisciplinary review. *J Med Internet Res* 2012;**14**:e80.
5. Fogg BJ. *Persuasive Technology: Using Computers to Change What We Think and Do?* San Francisco, CA: Morgan Kaufmann; 2003.
6. Khunti K. Near-patient testing in primary care. *Br J Gen Pract* 2010;**60**:157. http://dx.doi.org/10.3399/bjgp10X483454
7. Thacker SB, Stroup DF. Revisiting the use of the electronic fetal monitor. *Lancet* 2003;**361**:445–6. http://dx.doi.org/10.1016/S0140-6736(03)12465-8
8. Pammolli F, Riccaboni M, Oglialoro C, Magazzini L, Baio G, Salerno N. *Medical Devices Competitiveness and Impact on Public Health Expenditure*. Lucca: IMT Institute For Advanced Studies; 2005.
9. Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academies Press; 2001.
10. Healthcare Industries Task Force. *Better Healthcare Through Partnership: A Programme for Action*. London: Department of Health; 2004.
11. Greener I, Powell M. The changing governance of the NHS: reform in a post-Keynesian health service. *Hum Relat* 2008;**61**:617–36. http://dx.doi.org/10.1177/0018726708091764
12. Department of Health. *A Simple Guide to Payment by Results*. Leeds: Department of Health; 2012.
13. Robertson R, Jochelson K. *Interventions that Change Clinician Behaviour: Mapping the Literature*. London: The King's Fund; 2006.
14. Szczepura AK, Kankaanpää J. An Introduction to Health Technology Assessment. In Szczepura AK, Kankaanpää J, editors. *Assessment of Health Care Technologies: Case Studies, Key Concepts and Strategic Issues*. Chichester: John Wiley & Sons; 1996. pp. 3–16.
15. Global Harmonization Task Force Study Group 1. *Information Document Concerning the Definition of the Term 'Medical Device'*. The Global Harmonization Task Force; 2005.
16. Schreyögg J, Bäumler M, Busse R. Balancing adoption and affordability of medical devices in Europe. *Health Policy* 2009;**92**:218–24. http://dx.doi.org/10.1016/j.healthpol.2009.03.016
17. World Health Organization. *Medical Devices: Managing the Mismatch: An Outcome of the Priority Medical Devices Project*. Geneva: World Health Organization; 2010.
18. National Institute for Health and Clinical Excellence. *Interventional Procedures*; 2011. URL: www.nice.org.uk/guidance/ip/index.jsp (accessed 23 November 2012).
19. Lourenco T, Grant AM, Burr JM, Vale L. A framework for the evaluation of new interventional procedures. *Health Policy* 2012;**104**:234–40. http://dx.doi.org/10.1016/j.healthpol.2011.11.012

20. York Health Economics Consortium. *Organisational and Behavioural Barriers to Medical Technology Adoption.* Coventry: York Health Economics Consortium; 2009.
21. Hansson SO. Philosophy of medical technology. In Hansson SO, Anthonie M, editors. *Philosophy of Technology and Engineering Sciences*. Amsterdam: North-Holland; 2009. pp. 1275–300.
22. Webster A. Introduction: new technologies in health care: opening the black bag. In Webster A, editor. *New Technologies in Health Care: Challenge, Change and Innovation*. Basingstoke: Palgrave Macmillan; 2006. pp. 1–8.
23. Finch T, May C, Mort M, Mair F. Telemedicine, telecare and the future patient: innovation, risk and governance. In Webster A, editor. *New Technologies in Health Care: Challenge, Change and Innovation*. Basingstoke: Palgrave Macmillan; 2006. pp. 84–96.
24. Hendy J, Barlow J, Chrysanthaki T. Implementing remote care in the UK: an update of progress. *Eurohealth* 2011;**17**:21.
25. Frambach RT, Schillewaert N. Organizational innovation adoption: a multi-level framework of determinants and opportunities for future research. *J Business Res* 2002;**55**:163–76. http://dx.doi.org/10.1016/S0148-2963(00)00152-1
26. Williams I, Dickinson H. *Knowledge for Adoption: A Review of the Literature on Knowledge-Based Facilitators of Technology Adoption in Health Care*. Birmingham: Health Services Management Centre/NHS Institute for Innovation and Improvement; 2008.
27. Rogers EM. *Diffusion of Innovations*. 4th edn. New York, NY: Simon and Schuster; 1995.
28. Storey J, Fortune J, Johnson M, Savory C. The adoption and rejection patterns of practitioner-developed technologies: a review, a model and a research agenda. *Int J Innovation Manag* 2011;**15**:1043–67. http://dx.doi.org/10.1142/S1363919611003556
29. Lane PJ, Koka BR, Pathak S. The reification of absorptive capacity: a critical review and rejuvenation of the construct. *Acad Manag Rev* 2006;**31**:833–63. http://dx.doi.org/10.5465/AMR.2006.22527456
30. Straub ET. Understanding technology adoption: theory and future directions for informal learning. *Rev Educ Res* 2009;**79**:625–49. http://dx.doi.org/10.3102/0034654308325896
31. Department for Business, Indian Administration Service. *Strength and Opportunity 2011: The Landscape of the Medical Technology, Medical Biotechnology, Industrial Biotechnology and Pharmaceutical Sectors in the UK*. London: HM Government; 2011.
32. Department of Health. *High Cost Devices*; 2012. URL: www.dh.gov.uk/health/2012/03/high-cost-devices/ (accessed 28 November 2012).
33. Pate R. *What is Payment by Results?* London: Hayward Medical Communications; 2009.
34. NHS Improvement Programme. *Further Resources: Payments by Results (PbR)*; 2008. URL: www.improvement.nhs.uk/heart/sustainability/further_resources/pbr.html (accessed 7 January 2013).
35. Department of Health. *Payment by Results Guidance for 2012–13*. Leeds: Department of Health; 2012.
36. NHS Prescription Services. *Drug Tariff*; NHS Business Services Authority; 2012. URL: www.nhsbsa.nhs.uk/PrescriptionServices/924.aspx (accessed 28 November 2012).
37. Department of Health. *National Innovation Procurement Plan*. London: Department of Health; 2009.
38. Department of Health. *NHS Procurement: Raising Our Game*. London: Department of Health; 2012.

39. Department of Health. *World Class Procurement for the NHS: Call for Evidence and Ideas*. London: Department of Health; 2012.

40. Department of Health. *Academic Health Science Networks: Expressions of Interest*. London: Department of Health; 2012.

41. Kmietowicz Z. England gets five academic health science centres to compete on global stage. *BMJ* 2009;**338**:b10005.

42. National Institute for Health Research. *NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRCs)*; 2012. URL: www.nihr.ac.uk/infrastructure/Pages/CLAHRCs.aspx (accessed 29 November 2012).

43. Department of Health. *Breakthrough to Real Change in Local Healthcare: A Guide for Applications to Create Health Innovation and Education Clusters (HIECs)*. London: Department of Health; 2009.

44. Lourenco T, Grant A, Burr J, Vale L. Local decision-makers views' of national guidance on interventional procedures in the UK. *J Health Serv Res Policy* 2010;**15**(Suppl. 2):3–11. http://dx.doi.org/10.1258/jhsrp.2009.009090

45. Ong N, Redmayne G, Sarmah R. *The Development of a Tool for Assessing the Optimal Adoption of Healthcare Technologies in the NHS*. Brighton: Health and Care Infrastructure Research and Innovation Centre; 2009. pp. 7–23.

46. Hlatky MA, Lee KL, Harrell FE, Califf RM, Pryor DB, Mark DB, *et al.* Tying clinical research to patient care by use of an observational database. *Stat Med* 1984;**3**:375–84. http://dx.doi.org/10.1002/sim.4780030415

47. Tarricone R, Drummond M. Challenges in the clinical and economic evaluation of medical devices: the case of transcatheter aortic valve implantation. *J Med Market* 2011;**11**:221–9. http://dx.doi.org/10.1177/1745790411412242

48. Madden M. Alienating evidence based medicine vs. innovative medical device marketing: a report on the evidence debate at a Wounds conference. *Soc Sci Amp Med* 2012;**74**:2046–52. http://dx.doi.org/10.1016/j.socscimed.2012.02.026

49. Barnett J, Vasileiou K, Djemil F, Brooks L, Young T. Understanding innovators' experiences of barriers and facilitators in implementation and diffusion of healthcare service innovations: a qualitative study. *BMC Health Serv Res* 2011;**11**:342. http://dx.doi.org/10.1186/1472-6963-11-342

50. Sheldon TA, Cullum N, Dawson D, Lankshear A, Lowson K, Watt I, *et al.* What's the evidence that NICE guidance has been implemented? Results from a national evaluation using time series analysis, audit of patients' notes, and interviews. *BMJ* 2004;**329**:999. http://dx.doi.org/10.1136/bmj.329.7473.999

51. Hendy J, Barlow J. Adoption in practice: the relationship between managerial interpretations of evidence and the adoption of a healthcare innovation. *Health Policy Tech* 2013;**2**:216–21. http://dx.doi.org/10.1016/j.hlpt.2013.07.004

52. Lourenco T, Grant AM, Burr JM, Vale L. The introduction of new interventional procedures in the British National Health Service – a qualitative study. *Health Policy* 2011;**100**:35–42. http://dx.doi.org/10.1016/j.healthpol.2010.08.012

53. Sorenson C, Kanavos P. Medical technology procurement in Europe: a cross-country comparison of current practice and policy. *Health Policy* 2011;**100**:43–50. http://dx.doi.org/10.1016/j.healthpol.2010.08.001

54. Ahmad R, Kyratsis Y, Holmes A. When the user is not the chooser: learning from stakeholder involvement in technology adoption decisions in infection control. *J Hosp Infect* 2012;**81**:163–8. http://dx.doi.org/10.1016/j.jhin.2012.04.014

55. Lettieri E, Masella C. Priority setting for technology adoption at a hospital level: relevant issues from the literature. *Health Policy* 2009;**90**:81–8. http://dx.doi.org/10.1016/j.healthpol.2008.07.007

56. Fitzgerald L, Ferlie E, Wood M, Hawkins C. Evidence into practice? An exploratory analysis of the interpretation of evidence. In Dopson S, Mark A, editors. *Organisational Behaviour in Health Care: The Research Agenda*. Basingstoke: Palgrave Macmillan; 1999. pp. 189–206.

57. Fleck J, Howells J. Technology, the technology complex and the paradox of technological determinism. *Technol Anal Strat Manag* 2001;**13**:523–31. http://dx.doi.org/10.1080/09537320120095428

58. Llewellyn S, Northcott D. The average hospital. *Account Organ Soc* 2005;**30**:555–83. http://dx.doi.org/10.1016/j.aos.2004.05.005

59. March JG. Exploration and exploitation in organizational learning. *Organ Sci* 1991;**2**:71–87. http://dx.doi.org/10.1287/orsc.2.1.71

60. Hood C, Rothstein H, Baldwin R. *The Government of Risk: Understanding Risk Regulation Regimes*. Oxford: Oxford University Press; 2001.

61. Honigsbaum F. *The Division in British Medicine: History of the Separation of General Practice from Hospital Care, 1911–68*. London: Jessica Kingsley; 1984.

62. Llewellyn S. Purchasing power and polarized professionalism in British medicine. *Account Audit Accountabil J* 1997;**10**:31–59. http://dx.doi.org/10.1108/09513579710158702

63. Cullen J, Cohn S. Making sense of mediated information: empowerment and dependency. In Webster A, editor. *New Technologies in Health Care: Challenge, Change and Innovation*. Basingstoke: Palgrave Macmillan; 2006. pp. 112–30.

64. Ferlie E, Fitzgerald L, Wood M, Hawkins C. The nonspread of innovations: the mediating role of professionals. *Acad Manag J* 2005;**48**:117–34. http://dx.doi.org/10.5465/AMJ.2005.15993150

65. Turner BS. *Medical Power and Social Knowledge*. London: Sage Publications; 1987.

66. Hogg C. *Patients, Power and Politics: From Patients to Citizens*. London: Sage Publications; 1999.

67. Dent M. Changing jurisdictions within the health professions? Autonomy, accountability and evidence based practice. In Ackroyd S, Muzio D, editors. *New Directions in the Study of Expert Labour: Medicine, Law and Management Consultancy*. Basingstoke: Palgrave Macmillan; 2008. pp. 101–17.

68. Karsh BT. Beyond usability: designing effective technology implementation systems to promote patient safety. *Qual Saf Health Care* 2004;**13**:388–94. http://dx.doi.org/10.1136/qshc.2004.010322

69. Dusheiko M, Goddard M, Gravelle H, Jacobs R. *Trends in Health Care Commissioning in the English NHS: An Empirical Analysis*. York: Centre for Health Economics, University of York; 2006.

70. House of Commons Health Committee. *Commissioning, Fourth Report of Sessions 2009–10*. London: The Stationery Office Limited; 2010.

71. Public Accounts Committee. *The Procurement of Consumables by National Health Service Acute and Foundation Trusts.* London: The Stationery Office Limited; 2011.

72. Hendy J, Barlow J. The role of the organizational champion in achieving health system change. *Soc Sci Amp Med* 2012;**74**:348–55. http://dx.doi.org/10.1016/j.socscimed.2011.02.009

73. Williams R, Stewart J, Slack R. *Social Learning in Technological Innovation: Experimenting with Information and Communication Technologies*. Cheltenham: Edward Elgar Publishing; 2005.

74. Mackenzie D. Technological determinism. In Dutton WH, editor. *Society on the Line: Information Politics in the Digital Age*. Oxford: Oxford University Press; 1999. pp. 41–6.

75. Hameed MA, Counsell S, Swift S. A conceptual model for the process of IT innovation adoption in organizations. *J Engin Technol Manag* 2012;**29**:358–90. http://dx.doi.org/10.1016/j.jengtecman.2012.03.007

76. Robert G, Greenhalgh T, MacFarlane F, Peacock R. Adopting and assimilating new non-pharmaceutical technologies into health care: a systematic review. *J Health Serv Res Policy* 2010;**15**:243–50. http://dx.doi.org/10.1258/jhsrp.2010.009137

77. May C, Finch T, Mair F, Ballini L, Dowrick C, Eccles M, *et al.* Understanding the implementation of complex interventions in health care: the normalization process model. *BMC Health Serv Res* 2007;**7**:148. http://dx.doi.org/10.1186/1472-6963-7-148

78. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Q* 2004;**82**:581–629. http://dx.doi.org/10.1111/j.0887-378X.2004.00325.x

79. McLoughlin I. *Creative Technological Change: The Shaping of Technology and Organisations*. Oxford: Routledge; 1999. http://dx.doi.org/10.4324/9780203019870

80. Knights D, Murray F. *Managers Divided: Organisation Politics and Information Technology Management*. Chichester: John Wiley & Sons; 1994.

81. Dawson P, Buchanan D. The way it really happened: competing narratives in the political process of technological change. *Hum Relat* 2005;**58**:845–65. http://dx.doi.org/10.1177/0018726705057807

82. Neyland D, Woolgar S. Accountability in action?: the case of a database purchasing decision. *Br J Sociol* 2002;**53**:259–74. http://dx.doi.org/10.1080/00071310220133331

83. Grint K, Woolgar S. *The Machine at Work: Technology, Work and Organization*. Cambridge: Polity Press; 1997.

84. Latour B. *Science in Action: How to Follow Scientists and Engineers Through Society*. Cambridge, MA: Harvard University Press; 1987.

85. Callon M, Law J. On the construction of sociotechnical networks: content and context revisited. *Knowledge Soc* 1989;**8**:57–83.

86. Latour B. *Pandora's Hope: Essays on the Reality of Science Studies*. Cambridge, MA: Harvard University Press; 1999.

87. Latour B. On technical mediation – philosophy, sociology, genealogy. *Common Knowl* 1994;**3**:29–64.

88. Latour B. *Reassembling the Social: An Introduction to Actor-Network-Theory*. Oxford: Oxford University Press; 2005.

89. Callon M. Some elements of a sociology of translation: domestication of the scallops and the fishermen of St Brieuc Bay. In Law J, editor. *Power, Action and Belief: A New Sociology of Knowledge?* London: Routledge and Kegan Paul; 1986. pp. 196–233.

90. Latour B. The powers of association. In Law J, editor. *Power, Action and Belief: A New Sociology of Knowledge*. London: Routledge and Kegan Paul; 1986. pp. 264–80.

91. Law J, Callon M. Engineering and sociology in a military aircraft project: a network analysis of technological change. *Soc Problems* 1988;**35**:284–97. http://dx.doi.org/10.1525/sp.1988.35.3.03a00060

92. Latour B. Technology is society made durable. In Law J, editor. *A Sociology of Monsters. Essays on Power, Technology and Domination*. London: Routledge; 1991. pp. 103–31.

93. Edmondson AC, Bohmer RM, Pisano GP. Disrupted routines: team learning and new technology implementation in hospitals. *Adm Sci Q* 2001;**46**:685–716. http://dx.doi.org/10.2307/3094828

94. Prout A. Actor-network theory, technology and medical sociology: an illustrative analysis of the metered dose inhaler. *Sociol Health Illn* 1996;**18**:198–219. http://dx.doi.org/10.1111/1467-9566.ep10934726

95. Hall E. The 'geneticisation' of heart disease: a network analysis of the production of new genetic knowledge. *Soc Sci Med* 2005;**60**:2673–83. http://dx.doi.org/10.1016/j.socscimed.2004.11.024

96. Novek J. IT, gender, and professional practice: or, why an automated drug distribution system was sent back to the manufacturer. *Sci Technol Hum Values* 2002;**27**:379–403. http://dx.doi.org/10.1177/016224390202700303

97. Cussins C. Ontological choreography: agency for women patients in an infertility clinic. In Berg M, Mol A-M, editors. *Differences in Medicine: Unraveling Practices, Techniques and Bodies*. Durham, NC: Duke University Press; 1998. pp. 166–201.

98. Berg M. Accumulating and coordinating: occasions for information technologies in medical work. *Comput Support Coop Work* 1999;**8**:373–401. http://dx.doi.org/10.1023/A:1008757115404

99. Berg M. Patient care information systems and health care work: a sociotechnical approach. *Int J Med Informat* 1999;**55**:87–101. http://dx.doi.org/10.1016/S1386-5056(99)00011-8

100. Berg M, Bowker G. The multiple bodies of the medical record: toward a sociology of an artifact. *Sociol Q* 1997;**38**:513–37. http://dx.doi.org/10.1111/j.1533-8525.1997.tb00490.x

101. Berg M, Langenberg C, van den Berg I, Kwakkernaat J. Considerations for sociotechnical design: experiences with an electronic patient record in a clinical context. *Int J Med Informat* 1998;**52**:243–51. http://dx.doi.org/10.1016/S1386-5056(98)00143-9

102. Berg M. Implementing information systems in health care organizations: myths and challenges. *Int J Med Informat* 2001;**64**:143–56. http://dx.doi.org/10.1016/S1386-5056(01)00200-3

103. Bloomfield BP. The role of information systems in the UK National Health Service: action at a distance and the fetish of calculation. *Soc Stud Sci* 1991;**21**:701–34. http://dx.doi.org/10.1177/030631291021004004

104. Doolin B, McLeod L. Towards critical interpretivism in IS research. In Howcroft D, Trauth E, editors. *Handbook of Critical Information Systems Research: Theory and Application*. Cheltenham: Edward Elgar; 2005. pp. 244–71.

105. Bossen C. Test the artefact – develop the organization: the implementation of an electronic medication plan. *Int J Med Informat* 2007;**76**:13–21. http://dx.doi.org/10.1016/j.ijmedinf.2006.01.001

106. Cresswell KM, Worth A, Sheikh A. Actor-Network Theory and its role in understanding the implementation of information technology developments in healthcare. *BMC Med Informat Decis Making* 2010;**10**:67. http://dx.doi.org/10.1186/1472-6947-10-67

107. Nicolini D. Medical innovation as a process of translation: a case from the field of telemedicine. *Br J Manag* 2010;**21**:1011–26. http://dx.doi.org/10.1111/j.1467-8551.2008.00627.x

108. Law J, Hassard J. *Actor Network Theory and After*. Oxford: Blackwell; 1999.

109. McLean C, Hassard J. Symmetrical absence/symmetrical absurdity: critical notes on the production of actor–network accounts. *J Manag Stud* 2004;**41**:493–519. http://dx.doi.org/10.1111/j.1467-6486.2004.00442.x

110. Walsham G. Actor-network theory and IS research: current status and future prospects. In Lee A, Liebenau J, DeGross I, editors. *Information Systems and Qualitative Research*. London: Chapman & Hall; 1997. pp. 466–80.

111. Mutch A. Actors and networks or agents and structures: towards a realist view of information systems. *Organization* 2002;**9**:477–96. http://dx.doi.org/10.1177/135050840293013

112. Cresswell K, Worth A, Sheikh A. Implementing and adopting electronic health record systems: how actor-network theory can support evaluation. *Clin Govern* 2011;**16**:320–36. http://dx.doi.org/10.1108/14777271111175369

113. Greenhalgh T, Stones R. Theorising big IT programmes in healthcare: strong structuration theory meets actor-network theory. *Soc Sci Med* 2010;**70**:1285–94. http://dx.doi.org/10.1016/j.socscimed.2009.12.034

114. Taylor S, Todd PA. Understanding information technology usage: a test of competing models. *Inform Syst Res* 1995;**6**:144–76. http://dx.doi.org/10.1287/isre.6.2.144

115. Williams R, Edge D. The social shaping of technology. *Res Policy* 1996;**25**:865–99. http://dx.doi.org/10.1016/0048-7333(96)00885-2

116. Llewellyn S. Boundary work: costing and caring in the social services. *Account Organ Soc* 1998;**23**:23–47. http://dx.doi.org/10.1016/S0361-3682(96)00036-0

117. Llewellyn S. 'Two-way windows': clinicians as medical managers. *Organ Stud* 2001;**22**:593–623. http://dx.doi.org/10.1177/0170840601224003

118. Barjak F, Lane J, Kertcher Z, Poschen M, Procter R, Robinson S. Case studies of e-infrastructure adoption. *Soc Sci Comput Rev* 2009;**27**:583–600. http://dx.doi.org/10.1177/0894439309332310

119. Jirotka M, Procter R, Hartswood M, Slack R, Simpson A, Coopmans C, *et al.* Collaboration and trust in healthcare innovation: the eDiaMoND case study. *Comput Support Coop Work* 2005;**14**:369–98. http://dx.doi.org/10.1007/s10606-005-9001-0

120. Hartswood M, Procter R, Rouncefield M, Slack R. Making a case in medical work: implications for the electronic medical record. *Comput Support Coop Work* 2003;**12**:241–66. http://dx.doi.org/10.1023/A:1025055829026

121. Hartswood M, Procter R, Rouncefield M, Slack R. Performance management in breast screening: a case study of professional vision. *Cogn Technol Work* 2002;**4**:91–100. http://dx.doi.org/10.1007/s101110200008

122. Gieryn TF. *Cultural Boundaries of Science: Credibility on the Line*. Chicago, IL: University of Chicago Press; 1999.

123. Gieryn TF. Boundary-work and the demarcation of science from non-science: strains and interests in professional ideologies of scientists. *Am Sociol Rev* 1983;**48**:781–95. http://dx.doi.org/10.2307/2095325

124. Jasanoff S. *The Fifth Branch: Science Advisers as Policymakers*. Cambridge, MA: Harvard University Press; 1994.

125. Guston DH. Boundary organizations in environmental policy and science: an introduction. *Sci Technol Hum Values* 2001;**26**:399–408. http://dx.doi.org/10.1177/016224390102600401

126. Abbott A. *The System of Professions: An Essay on the Division of Expert Labor*. Chicago, IL: University of Chicago Press; 1988.

127. Suddaby R, Greenwood R. Rhetorical strategies of legitimacy. *Adm Sci Q* 2005;**50**:35–67.

128. Carlile PR. A pragmatic view of knowledge and boundaries: boundary objects in new product development. *Organ Sci* 2002;**13**:442–55. http://dx.doi.org/10.1287/orsc.13.4.442.2953

129. Burri RV. Doing distinctions boundary work and symbolic capital in radiology. *Soc Stud Sci* 2008;**38**:35–62. http://dx.doi.org/10.1177/0306312707082021

130. Hargadon A, Sutton RI. Technology brokering and innovation in a product development firm. *Adm Sci Q* 1997;**42**:716–49. http://dx.doi.org/10.2307/2393655

131. Bartel CA. Social comparisons in boundary-spanning work: effects of community outreach on members' organizational identity and identification. *Adm Sci Q* 2001;**46**:379–413. http://dx.doi.org/10.2307/3094869

132. Star SL, Griesemer JR. Institutional ecology, 'translations' and boundary objects: amateurs and professionals in Berkeley's Museum of Vertebrate Zoology, 1907–39. *Soc Stud Sci* 1989;**19**:387–420. http://dx.doi.org/10.1177/030631289019003001

133. Bechky BA. Sharing meaning across occupational communities: the transformation of understanding on a production floor. *Organ Sci* 2003;**14**:312–30. http://dx.doi.org/10.1287/orsc.14.3.312.15162

134. Kellogg KC, Orlikowski WJ, Yates JA. Life in the trading zone: structuring coordination across boundaries in postbureaucratic organizations. *Organ Sci* 2006;**17**:22–44. http://dx.doi.org/10.1287/orsc.1050.0157

135. Brown JS, Duguid P. Organizational learning and communities-of-practice: toward a unified view of working, learning, and innovation. *Organ Sci* 1991;**2**:40–57. http://dx.doi.org/10.1287/orsc.2.1.40

136. Wenger E. *Communities of Practice: Learning, Meaning, and Identity*. Cambridge, MA: Cambridge University Press; 1999.

137. Fox NJ. Boundary objects, social meanings and the success of new technologies. *Sociology* 2011;**45**:70–85. http://dx.doi.org/10.1177/0038038510387196

138. Edmondson AC, Winslow AB, Bohmer RM, Pisano GP. Learning how and learning what: effects of tacit and codified knowledge on performance improvement following technology adoption. *Decis Sci* 2003;**34**:197–224. http://dx.doi.org/10.1111/1540-5915.02316

139. Tabak F, Barr SH. Propensity to adopt technological innovations: the impact of personal characteristics and organizational context. *J Engin Technol Manag* 1999;**16**:247–70. http://dx.doi.org/10.1016/S0923-4748(99)00011-9

140. Holloway RM, Wilkinson C, Peters TJ, Russell I, Cohen D, Hale J, *et al.* Cluster-randomised trial of risk communication to enhance informed uptake of cervical screening. *Br J Gen Pract* 2003;**53**:620.

141. Cohen D, Longo MF, Hood K, Edwards A, Elwyn G. Resource effects of training general practitioners in risk communication skills and shared decision making competences. *J Eval Clin Prac* 2004;**10**:439–45. http://dx.doi.org/10.1111/j.1365-2753.2004.00503.x

142. Fleck J. *Innofusion or Diffusation?: The Nature of Technological Development in Robotics*. Edinburgh: Research Centre for Social Sciences, University of Edinburgh; 1988.

143. Yin RK. *Case Study Research: Design and Methods*. Thousand Oaks, CA: Sage Publications, Inc.; 2008.

144. Eisenhardt KM. Building theories from case study research. *Acad Manag Rev* 1989;**14**:532–50. http://dx.doi.org/10.5465/AMR.1989.4308385

145. Barnard KD, Lloyd CE, Skinner TC. Systematic literature review: quality of life associated with insulin pump use in type 1 diabetes. *Diabet Med* 2007;**24**:607–17. http://dx.doi.org/10.1111/j.1464-5491.2007.02120.x

146. National Diabetes Information Service. *Insulin Pump Audit – Findings for England*. 2010. URL: www.diabetes.org.uk/Documents/nhs-diabetes/insulin-pumps/insulin-pump-audit-final-report.pdf (accessed 12 January 2013).

147. O'Cathain A, Murphy E, Nicholl J. Why, and how, mixed methods research is undertaken in health services research in England: a mixed methods study. *BMC Health Serv Res* 2007;**7**:85. http://dx.doi.org/10.1186/1472-6963-7-85

148. Kvale S, Brinkmann S. *Interviews: Learning the Craft of Qualitative Research Interviewing*. Thousand Oaks, CA: Sage Publications, Inc.; 2008.

149. Savage J. Ethnography and health care. *BMJ* 2000;**321**:1400–2. http://dx.doi.org/10.1136/bmj.321.7273.1400

150. Bowen GA. Document analysis as a qualitative research method. *Qual Res J* 2009;**9**:27–40. http://dx.doi.org/10.3316/QRJ0902027

151. Bryman A. *Social Research Methods*. Oxford: Oxford University Press; 2012.

152. Karat J. User-centered software evaluation methodologies. *Handbook Hum-Comput Interact* 1997;**2**:689–704.

153. King N. Template analysis. In Symon G, Cassell C, editors. *Qualitative Methods and Analysis in Organizational Research: A Practical Guide*. Thousand Oaks, CA: Sage Publications Ltd; 1998. pp. 118–34.

154. Miles MB, Huberman AM. *Qualitative Data Analysis: An Expanded Sourcebook*. Thousand Oaks, CA: Sage Publications; 1994.

155. NHS Technology Adoption Centre. *Meet the Team*; 2013. URL: www.ntac.nhs.uk/AboutUs/Meet-the-Team.aspx (accessed 26 February 2013).

156. Cohen D, Billingsley M. Europeans are left to their own devices. *BMJ* 2011;**342**:d2748. http://dx.doi.org/10.1136/bmj.d2748

157. Ramsay G. *Teaching and Learning with Information and Communication Technology: Success through a Whole School Approach*. Education Resources Information Centre (ERIC); 2001.

158. Harty C. Implementing innovation in construction: contexts, relative boundedness and actor-network theory. *Construct Manag Econ* 2008;**26**:1029–41. http://dx.doi.org/10.1080/01446190802298413

159. Granovetter M. Economic action and social structure: the problem of embeddedness. *Am J Sociol* 1985;**91**:481–510. http://dx.doi.org/10.1086/228311

160. Akrich M. The de-scription of technical objects. In Bijker WE, Law J, editors. *Shaping Technology/Building Society*. Cambridge, MA: MIT Press; 1992. pp. 205–24.

161. Latour B, Woolgar S. *Laboratory Life: The Construction of Scientific Facts*. Princeton, NY: Princeton University Press; 1986.

162. Fox S. Communities of practice, Foucault and actor-network theory. *J Manag Stud* 2000;**37**:853–68. http://dx.doi.org/10.1111/1467-6486.00207

163. Latour B. On recalling ANT. In Law J, Hassard J, editors. *Actor Network Theory and After*. Chichester: John Wiley & Sons; 1999. pp. 23–34.

164. Law J. Notes on the theory of the actor-network: ordering, strategy, and heterogeneity. *System Prac Act Res* 1992;**5**:379–93. http://dx.doi.org/10.1007/BF01059830

165. Strathern M. Writing societies, writing persons. *History Hum Sci* 1992;**5**:5–16. http://dx.doi.org/10.1177/095269519200500101

166. Law J. *Power, Action, and Belief: A New Sociology of Knowledge?* London: Routledge & Kegan Paul; 1986.

167. Rycroft-Malone J, Seers K, Titchen A, Harvey G, Kitson A, McCormack B. What counts as evidence in evidence-based practice? *J Adv Nurs* 2004;**47**:81–90. http://dx.doi.org/10.1111/j.1365-2648.2004.03068.x

168. Dopson S, Locock L, Gabbay J, Ferlie E, Fitzgerald L. Evidence-based medicine and the implementation gap. *Health* 2003;**7**:311–30.

169. National Institute for Health and Clinical Excellence. *Past Technology Appraisals and Those Under Development*; 2012.URL: www.nice.org.uk/guidance/ta/indevelopment/index.jsp?p=off (accessed 30 August 2012).

170. Mackenzie PJ, Russell M, Ma PE, Isbister CM, Al Maberley D. Sensitivity and specificity of the optos optomap for detecting peripheral retinal lesions. *Retina* 2007;**27**:1119–24. http://dx.doi.org/10.1097/IAE.0b013e3180592b5c

171. Manivannan A, Plskova J, Farrow A, McKay S, Sharp PF, Forrester JV. Ultra-wide-field fluorescein angiography of the ocular fundus. *Am J Ophthalmol* 2005;**140**:525–7. http://dx.doi.org/10.1016/j.ajo.2005.02.055

172. Witmer MT, Kiss S. The clinical utility of ultra-wide-field imaging: a look at four widely available methods of imaging the peripheral retina that are making photography more clinically practical. *Rev Ophthalmol* 2012;**19**:60–5.

173. Mayers H. The Optos Panoramic200™ Scanning Laser Ophthalmoscope: advancing optometric practice. *Clin Refract Optom* 2004;**15**:156–67.

174. Khandhadia S, Madhusudhana KC, Kostakou A, Forrester JV, Newsom RSB. Use of Optomap for retinal screening within an eye casualty setting. *Br J Ophthalmol* 2009;**93**:52–5. http://dx.doi.org/10.1136/bjo.2008.148072

175. WebMD. *Eye Health Center*; 2013. URL: www.webmd.com/eye-health (accessed 26 February 2013).

176. Access Economics. *Future Sight Loss UK 1: Economic Impact of Partial Sight and Blindness in the UK Adult Population*. London: RNIB; 2009.

177. Hariprasad SM, Patel RD, Kitchens JW. *The Uncharted Realm of the Retinal Periphery*. 2011. URL: www.retinalphysician.com/articleviewer.aspx?articleid=105157 (accessed 20 December 2012).

178. Albert DM, Miller JW, Azar DT, Blodi BA. *Principles and Practice of Ophthalmology*. 3rd edn. Philadelphia, PA: Saunders; 2008.

179. Anderson D. *Optos: The Design Challenges and Business Tribulations*. Lecture at the Royal Society of Edinburgh, 10 March. London: The Royal Academy of Engineering and The Royal Society of Edinburgh; 2008.

180. Optos. *Product Description*; 2013. URL: www.optos.com/en-GB/Professionals/Ophthalmology/Product-description/ (accessed 26 February 2013).

181. Nath S, Sherman J, Battaglia M. Is OPTOS imaging additive or duplicative to a dilated fundus exam? *Invest Ophtalmol Visual Sci* 2005;**46**:E–Abstract 1554.

182. Friberg TR, Pandya A, Eller AW. Non-mydriatic panoramic fundus imaging using a non-contact scanning laser-based system. *Ophthal Surg Lasers Imag* 2003;**34**:488–97.

183. Silva PS, Cavallerano JD, Sun JK, Noble J, Aiello LM, Aiello LP. Nonmydriatic ultrawide field retinal imaging compared with dilated standard 7-field 35-mm photography and retinal specialist examination for evaluation of diabetic retinopathy. *Am J Ophthalmol* 2012;**154**:549–59. http://dx.doi.org/10.1016/j.ajo.2012.03.019

184. Ilett G, Kimber J. *Demand Management Scheme: The Community Ophthalmology Team*. UK: Practice-based Commissioning Workshop; 2007.

185. Berker T, Hartmann M, Punie Y, Ward K. *Domestication of Media and Technology*. Maidenhead: Open University Press; 2005.

186. Middleton D, Brown S. Net-working on a neonatal intensive care unit: the baby as virtual object. In Czarniawska B, Hernes T, editors. *Actor-Network Theory and Organizing*. Sweden: Liber and Copenhagen Business School Press; 2005. pp. 307–28.

187. National Institute for Health and Clinical Excellence (NICE). *Commissioning an Insulin Pump Therapy Service. Commissioning Guide – Implementing NICE Guidance*. London: NICE; 2009.

188. Lenhard MJ, Reeves GD. Continuous subcutaneous insulin infusion: a comprehensive review of insulin pump therapy. *Arch Intern Med* 2001;**161**:2293–300. http://dx.doi.org/10.1001/archinte.161.19.2293

189. Torrance T, Franklin V, Greene S. Insulin pumps. *Arch Dis Child* 2003;**88**:949–53. http://dx.doi.org/10.1136/adc.88.11.949

190. Scheiner G, Sobel RJ, Smith DE, Pick AJ, Kruger D, King J, *et al.* Insulin pump therapy: guidelines for successful outcomes. *Diabet Educ* 2009;**35**(Suppl. 2):29S–41S. http://dx.doi.org/10.1177/0145721709333493

191. Sherr J, Tamborlane WV. Past, present, and future of insulin pump therapy: better shot at diabetes control. *Mount Sinai J Med* 2008;**75**:352–61. http://dx.doi.org/10.1002/msj.20055

192. Jakisch BI, Wagner VM, Heidtmann B, Lepler R, Holterhus PM, Kapellen TM, *et al.* Comparison of continuous subcutaneous insulin infusion (CSII) and multiple daily injections (MDI) in paediatric type 1 diabetes: a multicentre matched-pair cohort analysis over 3 years. *Diabet Med* 2008;**25**:80–5. http://dx.doi.org/10.1111/j.1464-5491.2007.02311.x

193. Hoogma R, Hammond PJ, Gomis R, Kerr D, Bruttomesso D, Bouter KP, *et al.* Comparison of the effects of continuous subcutaneous insulin infusion (CSII) and NPH-based multiple daily insulin injections (MDI) on glycaemic control and quality of life: results of the 5-nations trial. *Diabet Med* 2006;**23**:141–7. http://dx.doi.org/10.1111/j.1464-5491.2005.01738.x

194. Doyle EA, Weinzimer SA, Steffen AT, Ahern JAH, Vincent M, Tamborlane WV. A randomized, prospective trial comparing the efficacy of continuous subcutaneous insulin infusion with multiple daily injections using insulin glargine. *Diabet Care* 2004;**27**:1554–8. http://dx.doi.org/10.2337/diacare.27.7.1554

195. Hirsch IB, Bode BW, Garg S, Lane WS, Sussman A, Hu P, *et al.* Continuous subcutaneous insulin infusion (CSII) of insulin aspart versus multiple daily injection of insulin aspart/insulin glargine in type 1 diabetic patients previously treated with CSII. *Diabet Care* 2005;**28**:533–8. http://dx.doi.org/10.2337/diacare.28.3.533

196. Raskin P, Bode BW, Marks JB, Hirsch IB, Weinstein RL, McGill JB, *et al.* Continuous subcutaneous insulin infusion and multiple daily injection therapy are equally effective in type 2 diabetes: a randomized, parallel-group, 24-week study. *Diabet Care* 2003;**26**:2598–603. http://dx.doi.org/10.2337/diacare.26.9.2598

197. Pickup J, Keen H. Continuous subcutaneous insulin infusion at 25 years: evidence base for the expanding use of insulin pump therapy in type 1 diabetes. *Diabet Care* 2002;**25**:593–8. http://dx.doi.org/10.2337/diacare.25.3.593

198. Diabetes Control and Complications Trial (DCCT) Research Group. Implementation of treatment protocols in the Diabetes Control and Complications Trial. *Diabet Care* 1995;**18**:361–76. http://dx.doi.org/10.2337/diacare.18.3.361

199. Diabetes Control and Complications Trial (DCCT) Research Group. Diabetes Control and Complications Trial (DCCT): the effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin dependent diabetes mellitus. *N Engl J Med* 1993;**329**:977–86. http://dx.doi.org/10.1056/NEJM199309303291401

200. Tamborlane WV, Bonfig W, Boland E. Recent advances in treatment of youth with type 1 diabetes: better care through technology. *Diabet Med* 2001;**18**:864–70. http://dx.doi.org/10.1046/j.1464-5491.2001.00626.x

201. Pickup J. Insulin pump therapy: pros and cons of continuous infusion. *Prescriber* 2009;**20**:12–16. http://dx.doi.org/10.1002/psb.541

202. National Institute for Health and Clinical Excellence (NICE). *Continuous Subcutaneous Insulin Infusion for the Treatment of Diabetes Mellitus. Review of Technology Appraisal Guidance 57*. London: NICE; 2008.

203. Department of Health. *Insulin Pump Services: Report of the Insulin Pumps Working Group*. London: Department of Health; 2007.

204. Medical Technology Group. *Pump Action – A Review of Insulin Pump Uptake and NICE Guidance in English Primary Care Trusts*. London: Medical Technology Group; 2010.

205. National Technology Adoption Centre. *How to Why to Guide: Continuous Subcutaneous Insulin Infusion*; 2010. URL: www.ntac.nhs.uk/HowToWhyToGuides/ContinuousSubcutaneousInsulinInfusion/Insulin-Infusion-Executive-Summary.aspx (accessed 12 February 2013).

206. National Technology Adoption Centre. *BNLA How to Why to Guide*; 2011. URL: www.ntac.nhs.uk/HowToWhyToGuides/BreastLymphNodeAssay/Breast-Lymph-Node-Assay-Executive-Summary.aspx (accessed 12 February 2013).

207. National Institute for Health and Clinical Excellence (NICE). *Early and Locally Advanced Breast Cancer: Diagnosis and Treatment*. London: NICE; 2009.

208. Luff P, Hindmarsh J, Heath C, editors. *Workplace Studies: Recovering Work Practice and Informing System Design*. Cambridge: Cambridge University Press; 2000.

209. Buscher M, Goodwin D, Mesman J, editors. *Ethnographies of Diagnostic Work: Dimensions of Transformative Practice*. Basingstoke: Palgrave Macmillan; 2010.

210. Haynes RB. Loose connections between peer-reviewed clinical journals and clinical practice. *Ann Intern Med* 1990;**113**:724–8. http://dx.doi.org/10.7326/0003-4819-113-9-724

211. Broom A, Adams J, editors. *Evidence-based Healthcare in Context: Critical Social Science Perspectives*. Farnham: Ashgate Publishing; 2012.

212. Fitzgerald L, Ferlie E, Wood M, Hawkins C. Interlocking interactions, the diffusion of innovations in health care. *Hum Relat* 2002;**55**:1429–49. http://dx.doi.org/10.1177/0018726021287822 13

213. Clement M, McDonald MD. Medical heuristics: the silent adjudicators of clinical practice. *Ann Intern Med* 1996;**124**:56–62. http://dx.doi.org/10.7326/0003-4819-124-1_Part_1-199601010-00009

214. Wilson CB. Surgery: adoption of new surgical technology. *BMJ* 2006;**332**:112. http://dx.doi.org/10.1136/bmj.332.7533.112

215. Brown N, Michael M. A sociology of expectations: retrospecting prospects and prospecting retrospects. *Technol Anal Strat Manag* 2003;**15**:3–18. http://dx.doi.org/10.1080/0953732032000046024

216. Cutress RI, McDowell A, Gabriel FG, Gill J, Jeffrey MJ, Agrawal A, *et al.* Observational and cost analysis of the implementation of breast cancer sentinel node intraoperative molecular diagnosis. *J Clin Pathol* 2010;**63**:522–9. http://dx.doi.org/10.1136/jcp.2009.072942

217. Stevens A, Milne R, Lilford R, Gabbay J. Keeping pace with new technologies: systems needed to identify and evaluate them. *BMJ* 1999;**319**:1291. http://dx.doi.org/10.1136/bmj.319.7220.1291

218. Ling T, Soper B, Marjanovic S, Celia C, Yaqub O, Reding A, *et al. Delivering the Aims of the CLAHRCs: Evaluating CLAHRCs' Strategies and Contributions. Interim Report: Phase 1*. Cambridge: Rand Europe; 2011.

219. Rycroft-Malone J, Wilkinson JE, Burton CR, Andrews G, Ariss S, Baker R, *et al.* Implementing health research through academic and clinical partnerships: a realistic evaluation of the Collaborations for Leadership in Applied Health Research and Care (CLAHRC). *Implement Sci* 2011;**6**:74. http://dx.doi.org/10.1186/1748-5908-6-74

220. Kyratsis Y, Ahmad R, Holmes A. Technology adoption and implementation in organisations: comparative case studies of 12 English NHS Trusts. *BMJ Open* 2012;**2**.

221. Simpson M, Buckman R, Stewart M, Maguire P, Lipkin M, Novack D, *et al.* Doctor–patient communication: the Toronto consensus statement. *BMJ* 1991;**303**:1385–7. http://dx.doi.org/10.1136/bmj.303.6814.1385

222. Eastaugh SR. Reducing litigation costs through better patient communication. *Phys Exec* 2004;**30**:36–8.

223. Coulter A, Entwistle V, Gilbert D. Sharing decisions with patients: is the information good enough? *BMJ* 1999;**318**:318–22. http://dx.doi.org/10.1136/bmj.318.7179.318

224. The King's Fund. *Where Next for the NHS Reforms? The Case for Integrated Care*. London: The King's Fund; 2011.

225. Kripalani S, LeFevre F, Phillips CO, Williams MV, Basaviah P, Baker DW. Deficits in communication and information transfer between hospital-based and primary care physicians. *JAMA* 2007;**297**:831–41. http://dx.doi.org/10.1001/jama.297.8.831

226. Field S. 'We cannot rest': perspectives on innovation, health and wealth. *Health Serv J* 2012 (Suppl. 31 May).

227. Smith J, Mays N, Dixon J, Goodwin N, Lewis R, McClelland S, *et al. A Review of the Effectiveness of Primary Care-led Commissioning and Its Place in the NHS*. London: Health Foundation; 2004.

228. Ham C. *Health Care Commissioning in the International Context: Lessons from Experience and Evidence*. Birmingham: Health Services Management Centre; 2008.

229. FitzGibbon F, Huckle D, Meenan BJ. Barriers affecting the adoption of point-of-care technologies used in chest pain diagnosis within the UK National Health Service: part 2 – manufacturer pricing and reimbursement policy issues. *Point Care* 2010;**9**:80–90.

230. Kane NM, Manoukian PD. The effect of the Medicare prospective payment system on the adoption of new technology. *N Engl J Med* 1989;**321**:1378–83. http://dx.doi.org/10.1056/NEJM198911163212006

231. Department of Health. *Payment by Results: Code of Conduct 2008*. London: Department of Health Publications; 2008.

232. Wilson T, Buck D, Ham C. Rising to the challenge: will the NHS support people with long term conditions? *BMJ* 2005;**330**:657–61. http://dx.doi.org/10.1136/bmj.330.7492.657

233. Farrar S, Yi D, Sutton M, Chalkley M, Sussex J, Scott A. Has payment by results affected the way that English hospitals provide care? Difference-in-differences analysis. *BMJ* 2009;**339**:b3047. http://dx.doi.org/10.1136/bmj.b3047

234. Christensen CM, Grossman JH, Hwang J. *The Innovator's Prescription: A Disruptive Solution for Health Care*. New York, NY: McGraw-Hill; 2009.

235. Hwang J, Christensen CM. Disruptive innovation in health care delivery: a framework for business-model innovation. *Health Affairs* 2008;**27**:1329–35. http://dx.doi.org/10.1377/hlthaff.27.5.1329

236. Brunsson N. Deciding for responsibility and legitimation: alternative interpretations of organizational decision-making. *Account Organ Soc* 1990;**15**:47–59. http://dx.doi.org/10.1016/0361-3682(90)90012-J

237. Ahrne G, Brunsson N. Organization outside organizations: the significance of partial organization. *Organization* 2011;**18**:83–104. http://dx.doi.org/10.1177/1350508410376256

238. McCafferty S, Williams I, Hunter D, Robinson S, Donaldson C, Bate A. Implementing world class commissioning competencies. *J Health Serv Res Policy* 2012;**17**(Suppl. 1):40–8. http://dx.doi.org/10.1258/jhsrp.2011.011104

239. Department of Health. *Equity and Excellence: Liberating the NHS*. London: HMSO; 2010.

240. Ham C. World class commissioning: a health policy chimera? *J Health Serv Res Policy* 2008;**13**:116–21. http://dx.doi.org/10.1258/jhsrp.2008.007177

241. Bovaird T. Developing new forms of partnership with the 'market' in the procurement of public services. *Public Adm* 2006;**84**:81–102. http://dx.doi.org/10.1111/j.0033-3298.2006.00494.x

242. Woodin J. *Healthcare Commissioning and Contracting*. Maidenhead: Open University Press; 2006.

243. Faulkner A. *Medical Technology into Healthcare and Society: a Sociology of Devices, Innovation and Governance*: Basingstoke: Palgrave Macmillan; 2009.

244. Keogh B. 'We cannot rest': perspectives on innovation, health and wealth. *Health Serv J* 2012; (Suppl. 6–7).

245. Pollock N, Williams R. The business of expectations: how promissory organizations shape technology and innovation. *Soc Stud Sci* 2010;**40**:525–48. http://dx.doi.org/10.1177/0306312710362275

246. Smith W. Theatre of use: a frame analysis of information technology demonstrations. *Soc Stud Sci* 2009;**39**:449–80. http://dx.doi.org/10.1177/0306312708101978

247. Brown N, Rappert B, Webster A. *Contested Futures: A Sociology of Prospective Techno-Science*. Aldershot: Ashgate; 2000.

248. Michael M. Futures of the present: from performativity to prehension. In Brown N, Rappert B, Webster A, editors. *Contested Futures: A Sociology of Prospective Techno-Science*. Aldershot: Ashgate; 2000. pp. 21–39.

249. Law J, Singleton V. Object lessons. *Organization* 2005;**12**:331–55. http://dx.doi.org/10.1177/1350508405051270

250. Grimshaw J, Eccles M, Thomas R, MacLennan G, Ramsay C, Fraser C, *et al.* Toward evidence-based quality improvement: evidence (and its limitations) of the effectiveness of guideline dissemination and implementation strategies 1966–1998. *J Gen Intern Med* 2006;**21**:S14–20. http://dx.doi.org/10.1111/j.1525-1497.2006.00357.x

251. Bak K, Dobrow M, Hodgson D, Whitton A. Factors affecting the implementation of complex and evolving technologies: multiple case study of intensity-modulated radiation therapy (IMRT) in Ontario, Canada. *BMC Health Serv Res* 2011;**11**:178. http://dx.doi.org/10.1186/1472-6963-11-178.

252. NHS Improving Quality. *Our Strategic Intent: NHS Improving Quality*. 2013. URL: www.england.nhs.uk/wp-content/uploads/2013/04/nhsiq-intent.pdf (accessed 2 March 2013).

253. Checkland K, Coleman A, Segar J, McDermott I, Miller R, Wallace A, *et al. Exploring the Early Workings of Emerging Clinical Commissioning Groups: Final Report*. UK: Policy Research Unit in Commissioning and the Healthcare System; 2012.

254. Right Care. *NHS Atlas of Variation in Healthcare Series*. URL: www.rightcare.nhs.uk/index.php/nhs-atlas/ (accessed 30 July 2013).

255. Boriani G, Burri H, Mantovani LG, Maniadakis N, Leyva F, Kautzner J, *et al.* Device therapy and hospital reimbursement practices across European countries: a heterogeneous scenario. *Europace* 2011;**13**(Suppl. 2):ii59–65. http://dx.doi.org/10.1093/europace/eur080

256. FitzGibbon F, Huckle D, Meenan BJ. Barriers affecting the adoption of point-of-care technologies used in chest pain diagnosis within the UK National Health Service: part 1 – user issues. *Point Care* 2010;**9**:70–9.

257. Gratwohl A, Schwendener A, Baldomero H, Gratwohl M, Apperley J, Niederwieser D, *et al.* Changes in the use of hematopoietic stem cell transplantation: a model for diffusion of medical technology. *Haematologica* 2010;**95**:637–43. http://dx.doi.org/10.3324/haematol.2009.015586

258. Sharma U, Barnett J, Clarke M. Clinical users' perspective on telemonitoring of patients with long term conditions: understood through concepts of Giddens's structuration theory & consequence of modernity. *Stud Health Technol Informat* 2010;**160**:545–9.

259. Williams I, Dickinson H. Can knowledge management enhance technology adoption in healthcare? A review of the literature. *Evidence Policy* 2010;**6**:309–31. http://dx.doi.org/10.1332/174426410X524811

# Appendix 1 Text of information sheet for research participants

## Background

Evidence indicates that patient safety and proven clinical effectiveness is insufficient to ensure the adoption and implementation of new technologies, and that the organisational and policy context may present barriers which slow or even prevent uptake. Despite government policy, innovative technologies are not yet demand-led through commissioning. Introducing new technologies initially raises providers' costs as they necessitate training, can encounter clinical resistance, may alter the patient pathway and, therefore, patient management, and can lead to reduced patient throughput. The current funding regime of Payment by Results (PbR) rewards activity and as such it is not surprising that providers see new technologies as risky. Moreover, clinical utility has to be built and demonstrated as technologies are embedded in concrete interdisciplinary work practices along the adoption pathway.

## The aims of this research are

- To identify the root causes of risk perceptions over technology adoption in the 'sponsoring' trusts.
- To map out the network of actors required for successful technology adoption.
- To understand the policy, organisational and cognitive barriers and resolve cross-boundary issues.
- To assess the extent to which PbR is creating barriers to technology adoption and implementation.

## The technologies we are researching

Our focus is on technologies which give rise to the greatest perceptions of risk along the lines outlined above. Discussions with the NTAC led to the identification of *three* technologies presenting the most complex problems of adoption and implementation. These are:

1. an insulin pump with remote patient management
2. a lymph node metastases diagnostic for breast cancer
3. a system for advanced retinal imaging.

## Data collection

We are collecting primary data on adoption and implementation difficulties with the three technologies over nine sites. Structured comparisons will be made between the project sites and the network dynamics within them. There will also be a focus on the specific areas of difficulty at each of the sites.

## Your role in the research

To achieve these ends we are conducting semistructured interviews with clinicians and managers. These interviews (we anticipate that at each trust there will be 8–12 key players) take about 1 hour and, if participants are agreeable, we would like to tape and transcribe them. We also hope to 'sit-in' on two to three formal meetings if technology adoption is still a substantive agenda item and spend time (1 day) tracking the informal interactions of one to two key players in technology adoption as they go about their

normal work or if this is not feasible to ask participants at interview to sketch their personal network maps. Agreeing to participate is voluntary and you (at trust or individual level) can *opt out at any stage* if you wish.

## The benefit to you

Participation in this research should crystallise adoption and implementation problems. If your trust is still experiencing difficulties the researchers act as 'cross fertilisers' so that you can learn from the experiences of other trusts. You will have access to the research report and, if you wish, participate in the publications that flow from the research.

We hope that you will be able to participate in this research. Please contact us if you have any questions.

# Appendix 2 Interview guide

Some questions will be more relevant than others dependent on the role of the participant so questions may be omitted or probed further as appropriate. Semistructured format. All interviews in a face-to-face situation at the trust. All answers to be taped and transcribed, if acceptable to participants.

## General questions

Q1. Please will you outline your role in working towards the successful adoption and implementation of (name of specific clinical technology).

Q2. What are the main clinical benefits of (name of specific clinical technology)?

Q3. What do you think are the main organisational barriers to adoption and implementation?

Prompt: raises costs; funding issues; organisational inertia; clinical resistance; managerial resistance; difficulty in forming the business case; commissioning issues.

Q4. What do you think are the main policy barriers to adoption and implementation?

Prompt: PbR; organisational targets (e.g. waiting lists); competing policy objectives; rapid policy reform.

Q5. Are there any unresolved clinical barriers to adoption and implementation?

Q6. Do you believe that adopting and implementing (name of specific clinical technology) is risky? If yes, how is this risk perceived? How is this risk alleviated?

## Building a support network

Q7. Was there a key individual who championed the adoption of (name of specific clinical technology)? If yes, why was this person so crucial and would the technology have been adopted without them?

Q8. Who are the key individuals *in the trust* whose support was required for successful adoption?

Q9. Who are the key individuals *outside of the trust* whose support was required for successful adoption?

Q10. What were the main issues in building this network of support?

Q11. Has this network been sustained? If yes, how? If no, why?

Q12. Were there any individuals who were resistant to the adoption of (name of specific clinical technology)? If yes, why were they resistant? How was their co-operation secured?

Q13. Did successful adoption necessitate the creation of new organisational roles? If yes, what were these roles? Did any of these roles cross boundaries?

Prompt: between the trust and commissioners; between the trust and suppliers; across different specialisms within the trust.

## Payment by Results and funding issues

Q14. Do you think that PbR created particular difficulties for the introduction of (name of specific clinical technology)? If yes, what were these?

Q15. Is the trust engaged in strategies to try to resolve these difficulties? If yes, what are these strategies?

Q16. Do you believe that (name of specific clinical technology) will eventually raise productivity? If yes, why? If no, why not?

Q17. Did the introduction of HRG4 impact on (name of specific clinical technology)? If yes, what was the impact?

Q18. Is the trust engaged in any new costing initiatives as a result of the introduction of (name of specific clinical technology)?

## User acceptability issues

Q19. Were there clinical user acceptability issues in relation to (name of specific clinical technology)? If yes, what were these and how were these overcome?

Q20. Were work processes disrupted due to the introduction of (name of specific clinical technology)? If yes, what form did this disruption take and how was it overcome?

Q21. Will the benefits of the introduction of (name of specific clinical technology) accrue solely within the trust or will there be benefits outside?

Prompt: primary care; home care.

## Patient acceptability issues

Q22. Were there any patient acceptability issues in relation to (name of specific clinical technology)? If yes, what were these and how were these overcome?

Q23. Does the effective use of (name of specific clinical technology) require patient/carer compliance/involvement/knowledge? If yes, what work with patients/carers was required to ensure the effective use of the technology?

Q24. Were patients involved in either the adoption or implementation processes? If yes, what form did this involvement take?

Q25. Has patient feedback on (name of specific clinical technology) been sought? If yes, are you aware of any issues that this feedback raised?

## Supplier/industry issues

Q26. Was the trust encouraged by the producers of (name of specific clinical technology) to adopt? If yes, how was this manifested?

Q27. Was the trust well supported by the producers of (name of specific clinical technology)? If yes, what form did this support take? If no, what problems did this create?

## Engagement with the NHS Technology Adoption Centre

Q28. How has your engagement with the NTAC assisted in the adoption and implementation of (name of specific clinical technology)?

Q29. Do you believe that there would have been adoption without the NTAC's support?

Q30. Is your engagement with the NTAC still ongoing? If yes, what form does this take?

Q31. Has the NTAC produced a 'How to Why to' guide for (name of specific clinical technology)?

Q32. Will this 'How to Why to' guide be of any relevance to you? Or do you think that your adoption process can now be considered complete?

Q33. Do you know if the NTAC has produced any other 'How to Why to' guide for another technology which you are considering adopting? If yes, have you downloaded this guide? How has the guide helped you?

## Closing questions

Q34. Do you believe that the difficulties the trust experienced in adopting (name of specific clinical technology) are specific or would they apply to other technologies?

Q35. Do you think that best practice can be prescribed for technology adoption? If yes, can you indicate what form this would take?

Q36. Reflecting on the adoption and implementation process for (name of specific clinical technology), if you were to undertake this process again what would you do differently and why?

Thank you for agreeing to participate in this research.

# Appendix 3 Online survey invitation and questions

Dear colleague

We are a team at the University of Manchester, who are funded by the Department of Health to carry out research into the use of Continuous Subcutaneous Insulin Infusion (CSII). We should be most grateful if you would complete this short online survey (link below).
http://mbs.qualtrics.com/SE/?SID=SV_8GGz0M0tvemXOxC

All responses are completely anonymous and will contribute to the analysis in our final report (findings to be published summer 2013).

If you require any further information please contact me using the details below.

Best wishes

Chris
**Chris Wood | Herbert Simon Institute**
Manchester Business School | The University of Manchester | Room 8.40 Harold Hankins Building | Booth Street West | Manchester M15 6PB | Tel +44(0) 161 275 0550 | chris.wood@mbs.ac.uk | http://research.mbs.ac.uk/hsi

**This survey explores issues relating to Continuous Subcutaneous Insulin Infusion (CSII). It contains 7 multiple choice questions and should take no more than 3 minutes to complete.**

**Have you been involved, at your Trust, with increasing the number of patients with Type 1 diabetes who use CSII?**

If no, please go to end of survey.

- ○ Yes
- ○ No

**If yes, could you estimate the current percentage of patients, at your Trust, with Type 1 diabetes who are now using CSII?**

- ☐ 0 - 5 %
- ☐ 5 - 10 %
- ☐ 10 - 15 %
- ☐ Over 15 %
- ☐ Unknown

**Please could you now estimate the percentage of patients, at your Trust, with Type 1 diabetes that were using CSII three years ago?**

- ☐ 0 - 5 %
- ☐ 5 - 10 %
- ☐ 10 - 15 %
- ☐ Over 15 %
- ☐ Unknown

**Are you aware of an organisation called the NHS Technology Adoption Centre (NTAC)?**

If no, go to end of survey.

- ○ Yes
- ○ No

**On their website, the NHS Technology Adoption Centre (NTAC) have a 'How-To, Why-To' (HTWT) guide for CSII adoption and implementation, are you aware of this guide?**

If no, go to end of survey.

- ○ Yes
- ○ No

If yes, have you used this guide for (tick all that apply)

- ☐ A business case to your Trust to develop your CSII service
- ☐ A business case to your commissioners to develop your CSII service
- ☐ A information resource about CSII
- ☐ To contact other Trusts with experience of developing their CSII service

On a scale of 1-5 how helpful did you find the NTAC HTWT CSII guide?

| 1 (Extremely unhelpful) | 2 (Somewhat unhelpful) | 3 (Neutral) | 4 (Somewhat helpful) | 5 (Extremely helpful) |
|---|---|---|---|---|





**Please use the box below for any further comments**

Thank you for your time

# Appendix 4 Summaries of recent research publications relevant to technology adoption in the NHS

| Authors and date published | Technology | Data and methods | Conclusions and outputs regarding factors affecting technology adoption and implementation |
|---|---|---|---|
| Ahmad *et al.* 2012;[54] Kyratsis *et al.* 2012[220] | HCAI technologies | Case studies of 10 acute care and one primary care recipients of the HCAI Technology Innovation Award (2009), which provided funding for them to adopt new technologies. Based on individual and group interviews with 109 informants, covering 49 technologies | Three types of innovation knowledge influence decision-making: 'awareness' (information that an innovation exists); 'principles' (information about an innovation's functioning principles); and 'how-to' (information required to use an innovation properly at individual and organisational levels). Early consideration of 'how-to' knowledge by decision-makers is associated with successful adoption and implementation, and late consideration is associated with various negative consequences. Horizontal professional networks are influential<br><br>Appropriate stakeholder involvement at each stage of the process can be beneficial, and should be considered as part of the initial planning |
| Madden 2012[48] | Wound-care products | Participant observation of the 2010 Wounds UK conference/ trade show | The conference presentations are like 'infomercials' – although there is an emphasis on providing information, there is no scrutiny of the underlying reasoning. Many clinicians feel undervalued and appreciate the uncritical value presenters place on clinical experience (as opposed to rigorous research evidence, which is lacking). The marketing approach may be related to the lack of radical innovations in this field |
| Hendy and Barlow 2011;[51] Hendy and Barlow 2012[72] | Telecare – remote monitoring of chronically ill patients or frail elderly people | Case studies of eight (three in one study, five in the other) health and social care organisations that were 'frontrunners' in developing telecare in England. Utilised interviews, observations, document analysis, informal discussions and meetings | Champions are effective in the early stages of adoption when change is contained within small, bounded areas of practice, such as pilot projects. Whether or not they remain helpful in spreading innovation more widely across the organisation is influenced by the 'champion' being able to establish an identification with the new circumstances |

| Authors and date published | Technology | Data and methods | Conclusions and outputs regarding factors affecting technology adoption and implementation |
|---|---|---|---|
| | | | Managers promoting remote care shaped 'evidence' to align it with their practices and, to a varying extent, with wider organisation goals. Where managers felt they were losing control or 'being taken over', then spread was markedly slower |
| Lourenco *et al.* 2011;[52] Lourenco *et al.* 2012;[19] Lourenco *et al.* 2010[44] | New interventional procedures (involving an incision, puncture, entry into a body cavity or the use of electromagnetic radiation) | Interviews with 14 NHS decision-makers from England (nine interviewees), Wales (one interviewee) and Scotland (four interviewees), whose roles were thought likely to influence the uptake of new interventional procedures. The interviews were conducted in 2008 | The extent to which the decision-making process for introducing new procedures was a structured and transparent one varies greatly between providers, and this can affect safety and efficiency. Where there were cost implications, business cases were prepared. Decisions were influenced by various factors, including manufacturer incentives; support from colleagues; the extent of innovation; who is involved; evidence on prevalence, incidence, safety, efficacy, effectiveness, cost-effectiveness and training needs; public or policy-maker pressure; horizon scanning; whether or not other commissioners offer similar treatments; whether or not strategic priorities are met; and NICE guidance. Although the overriding factor was the overall balance of benefits and costs, immediate cost and resource requirements were also very important<br><br>There was a lack of co-ordination between providers and commissioners regarding decisions about the adoption of new procedures, and commissioners were reactive rather than proactive. NICE guidance was often regarded as not providing commissioners with the range of contextual information they needed<br><br>Monitoring of the use of procedures could also be improved<br><br>Proposes a four-stage framework for the evaluation of interventional procedures over time: development; efficacy and short-term safety; effectiveness and cost-effectiveness; implementation. EU regulatory authorities only cover part of stage 1 (safety not clinical benefit), and NICE assessments typically |

| Authors and date published | Technology | Data and methods | Conclusions and outputs regarding factors affecting technology adoption and implementation |
|---|---|---|---|
| | | | cover only stages 1 and 2. Greater pre-market evaluation of high-risk technologies at stages 1 and 2 should be considered, together with mandatory post-market data collection to fulfil stages 3 and 4 |
| Bak *et al.* 2011[251] | IMRT | Case studies of four purposively selected, publicly funded cancer centres in Ontario, Canada. The authors specifically highlight that the results are likely to be relevant to the UK. Document analysis plus interviews with 18 key informants actively involved in IMRT implementation, including radiation oncologists, medical physicists, radiation therapists and senior cancer centre administrators | Develops a five-stage framework for technology adoption and implementation (adapted from Rogers 1995[27]), which details various enabling factors and barriers:<br>• Pre- and post-implementation – evidence, wait times<br>• Pre-implementation – leadership, resources, resistance to change<br>• Implementation – implementation teams, training, expertise, standardisation, collaboration |
| Barnett *et al.* 2011[49] | Service innovations, all except one or two not involving new technology | Five primary and 10 secondary health-care organisations in the UK, which had received health service journal awards from 2007 to 2009 for successfully generating and implementing service innovations, were studied (30% of the 51 approached). In-depth, semistructured interviews were conducted with the organisational representatives (typically a single key informant for each case) who conceived and led the development process<br><br>Accommodating a new technology was not the principal driver for innovation, and only 1, or at most 2, out of 15 innovations studied incorporated new technology | For decision-making, 'hard' quantitative evidence was valued over qualitative evidence and experience. Horizontal professional networks were seen as crucial to diffusion, with professional group boundaries being a barrier. Congruence with the organisational culture was important, as were human and financial resources. Adaptation to new contexts was necessary. The main external influences identified were economic (e.g. cost containment), political (e.g. regulators) and ideological (e.g. fitting the 'spirit of the times') |
| Boriani *et al.* 2011[255] | CIEDs | Tabulates data on reimbursement practices for CIEDs in a sample of European countries, including the UK | Tariffs are not available in the UK for all types and uses of this technology, which may restrict beneficial usage. More generally, evaluation and reimbursement practices, such as frequency of updating DRG tariffs, can affect the take-up of technologies and affect incentives for innovation. It is important that processes for DRG development, deployment and updating are robust and transparent, involve clinicians and ensure accurate clinical coding |

| Authors and date published | Technology | Data and methods | Conclusions and outputs regarding factors affecting technology adoption and implementation |
|---|---|---|---|
| Sorenson and Kanavos 2011[53] | A medical aid (incontinence pads) and three implantable artificial body parts (implantable cardioverter-defibrillators, coronary stents and knee endoprostheses) | Conducted a literature review and interviews with 35 key informants to investigate the public procurement of technologies in England, France, Germany, Italy and Spain | The balance between quality and cost considerations in purchasing decisions varies, with quality tending to be given greater weight for more complex, less standardised technologies. Factors often considered include the quality of the service as a whole, reliability, production capacity/volume, delivery date, maintenance requirements and technical merit. Therapeutic benefit and cost-effectiveness are not considered so frequently. There have been initiatives in the English NHS in recent years aiming to give greater emphasis to value for money rather than cost containment, but there are technical difficulties in evaluating medical devices, and the capacity of organisations involved in purchasing needs to be increased. Greater and more formal use of clinician expertise in purchasing decisions might be beneficial |
| Storey *et al.* 2011[28] | Innovative technologies | Literature review (no further details are provided) | Five key characteristics affecting adoption are relative advantage over existing technologies and procedures; compatibility with existing structures and processes; complexity – how difficult it is to use, and whether or not it matches the complexity of the situation in which it is used; whether or not the technology has been trialled in the NHS and can be trialled by the prospective adopter; and whether or not the technology can be observed in action in the NHS prior to adoption. Scale and cost are also factors<br><br>Adoption is a process where context is likely to be important, including the absorptive capacity of the receiving organisation<br><br>Suggests that future research is based on tracing the 'adoption activity pathway' |
| FitzGibbon *et al.* 2010;[229] FitzGibbon *et al.* 2010[256] | POCT | Survey to assess the value of cardiac marker POCT in chest pain diagnosis. There were 100 respondents (physicians, nurses and laboratory scientists) from 10 major hospitals within the five Northern Ireland NHS trusts. | Respondents said the main drivers for POCT uptake were patient convenience, patient demand and improved clinical management. Clinical outcome studies (which are extensive) were the main influence on |

| Authors and date published | Technology | Data and methods | Conclusions and outputs regarding factors affecting technology adoption and implementation |
|---|---|---|---|
| | | Twenty-eight respondents were actual end-users<br><br>Survey of POCT device manufacturers in the UK | adoption decisions, rather than economics or government policy, despite a policy push<br><br>Barriers to uptake include cost (despite strong evidence of cost-effectiveness), accuracy, implementation, regulation, quality assurance and accreditation. Incentives might include better training and quality assurance, greater reimbursement and reduced accreditation fees. Costs include those of interfacing POCT with existing IT systems. End-users should be involved in health technology appraisals early in the product life cycle, to identify likely implementation problems and facilitate integration<br><br>NHS procurement has emphasised cost rather than value and has also given lower priority to capital equipment. Issues regarding the tariff are also identified |
| Gratwohl *et al.* 2010[257] | HSCTs | Multivariate statistical regression to investigate the association of micro- and macro-level factors with numbers of HSCTs. Data on 251,106 cell transplants from 591 teams in 36 European countries, including the UK, were analysed | Economics, evidence, external regulations and expectations are likely to be key factors affecting the adoption of a medical technology |
| Robert *et al.* 2010[76] | Technological innovations (device, procedure or organisational support system discontinuous with previous practice) | Systematic review focusing on organisational factors affecting adoption and assimilation in the NHS in England | Factors highlighted: history, culture, interprofessional relationships; power and politics; formal and informal decision-making processes; complex social influences; professional boundaries; importance of senior clinicians to decision-making; external networks. These factors interact in a complex way<br><br>Suggests that the Normalization Process Model may be relevant. This has four components: interactional workability; relational integration; skill set workability; and contextual integration |
| Sharma *et al.* 2010[258] | Telemonitoring of patients with long-term conditions such as heart failure and | Three focus group discussions with a total of 16 clinical users (nurses and technicians) prior to the launch of a telehealth service | Conflict and contradiction – concerns about working with the technology – can arise if staff lack feelings of |

| Authors and date published | Technology | Data and methods | Conclusions and outputs regarding factors affecting technology adoption and implementation |
|---|---|---|---|
| | obstructive pulmonary disease | in Nottingham, UK, to elicit their initial perceptions about the service | trust in the actors involved and of security in their jobs and identities. These played an important role in decisions about whether to use a telehealth system. Suggests involving users in the decision-making process in order to help establish trust and security |
| Lettieri and Masella 2009[55] | Equipment, medical devices and information systems | Literature review covering priority setting for the adoption of new technology at a hospital level, i.e. how value can be generated. Papers regarding implementation success (sustainable use of the technology) and failure factors were also reviewed<br><br>Appears to be based largely on non-UK research, particularly from the USA | Derives a two-dimensional reference framework for priority setting at hospital level. When deciding on technology adoption, consideration should be given to the expected contribution to value generation (social, economic and knowledge) over the short and long term, and to the level of sustainability (economic, organisational, technological, resource and context) |
| Ong *et al.* 2009[45] | Technology that is 'ready for market' | Research commissioned by NTAC, comprising a literature review; stakeholder interviews with nine people, including procurement managers, academic health technology experts and senior NHS managers; and a stakeholder workshop | Stakeholders vary in the extent to which they value profit, competitive advantage and utility in their technology adoption decisions<br><br>There are inevitable uncertainties about costs, risks and benefits, which can change over time<br><br>Develops a methodology that could be used by NHS managers and policy-makers to determine how many units of a particular technology would provide maximum benefit over cost (e.g. how many insulin pumps are needed to manage a local population of diabetic patients?). However, acknowledges that central planning is not in vogue in the NHS, and suggests an advisory role for clinical networks |
| Schreyögg *et al.* 2009[16] | Medical devices (medical aids, implants and artificial body parts, technical equipment for professionals) | Analyses the policies of four EU countries, including the UK, regarding balancing access to new medical devices with cost control | Coverage should be determined by governments on the basis of independent assessment of the evidence for cost-effectiveness of both new and existing products. Fixed reimbursement rates (e.g. reference prices) based on actual costs should be used to contain costs, with spending caps a last resort |

| Authors and date published | Technology | Data and methods | Conclusions and outputs regarding factors affecting technology adoption and implementation |
|---|---|---|---|
| York Health Economics Consortium 2009[20] | Medical technologies (types include service changes, IT and new models of care, medical equipment) | Commissioned by the NHSI and NTAC. A literature review, discussion with experts and in-depth interviews with 40 senior NHS managers from 25 provider and commissioner organisations | Challenges to successful technology adoption include communication; financial issues; evidence base; time constraints; champions, project leaders and facilitators; training and education; staff resistance; external relationships; the nature of the technology; infrastructure; staffing levels; management; political context. These are, however, by no means exhaustive<br><br>For many of the highlighted challenges there are corresponding methods that have been used to try to address them. Further methods include staff engagement, systematic introduction, administrative support and culture |
| Williams and Dickinson 2008;[26] Williams and Dickinson 2010[259] | Innovations in health-care settings (including pharmaceuticals, IT and models of service improvement) | A pragmatic rather than exhaustive literature review, examining the role of knowledge-based interventions in technology adoption. A significant proportion of the literature was from the USA | The evidence base should cover implementation and provide tools for adopters which focus on enhancing absorptive capacity; technology design and production should involve end-users; facilitated interaction, training and nurturing of champions are promising practices which should be investigated further, as should decommissioning of superseded technologies |

CIED, cardiac implantable electrical device; HCAI, health-care-associated infection; HSCT, haematopoietic stem cell transplant; IMRT, intensity-modulated radiation therapy; POCT, point-of-care diagnostic testing.

EME
**HS&DR**
HTA
PGfAR
PHR

Part of the NIHR Journals Library
www.journalslibrary.nihr.ac.uk



***Published by the NIHR Journals Library***